

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**A COMPARISON OF MEDICAID
FEDERAL UPPER LIMIT AMOUNTS
TO ACQUISITION COSTS,
MEDICARE PAYMENT AMOUNTS,
AND RETAIL PRICES**



Daniel R. Levinson
Inspector General

August 2009
OEI-03-08-00490

Office of Inspector General

<http://oig.hhs.gov>

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

Office of Audit Services

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

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.



EXECUTIVE SUMMARY

OBJECTIVES

1. To determine how Federal upper limit (FUL) amounts calculated under the current method compare to (a) pharmacy acquisition costs, (b) Medicare Part D payment amounts, and (c) retail prices under discount generic programs.
2. To estimate the financial impact on the Medicaid program of continuing to calculate FUL amounts using the current method.
3. To determine how FUL amounts calculated under the method required by the Deficit Reduction Act of 2005 (DRA) compare to the pricing points under review.

BACKGROUND

Federal regulations require, with certain exceptions, that each State Medicaid agency's reimbursement for a covered outpatient drug not exceed (in the aggregate) the lower of the estimated acquisition cost plus a reasonable dispensing fee or the provider's usual and customary charge to the public for the drugs. For certain drugs, States also use the FUL program or State maximum allowable cost programs in setting reimbursement.

The FUL program was established to help ensure that Medicaid takes advantage of lower market prices for multiple-source drugs. However, previous Office of Inspector General (OIG) work consistently found that the published prices used to set Medicaid FUL amounts often greatly exceeded prices in the marketplace. Based in part on this work, the DRA required that, beginning January 1, 2007, FULs be based on 250 percent of the lowest average manufacturer price (AMP) rather than 150 percent of the lowest price published in national compendia.

In connection with a lawsuit filed by two trade associations representing retail pharmacies, a Federal judge issued a preliminary injunction preventing the Centers for Medicare & Medicaid Services (CMS) from moving forward with AMP-based reimbursement under Medicaid. In addition, the Medicare Improvements for Patients and Providers Act of 2008 statutorily delayed the implementation of the new FUL methodology until October 2009. As a result, CMS is still basing FULs on the pre-DRA method as of August 2009.

We compared FUL amounts calculated under the current pre-DRA method and the proposed AMP-based method to three pricing points: (1) estimated fourth-quarter 2007 pharmacy acquisition costs for the 50 FUL drugs with the highest total Medicaid expenditures in 2007, (2) average Part D pharmacy reimbursement amounts for all FUL drugs in the fourth quarter of 2007, and (3) retail pricing for any FUL drugs included in selected companies' discount generic programs. We estimated pharmacy acquisition costs based on information obtained from wholesale distributors of prescription drugs. To estimate the financial impact of continuing to base FUL amounts on the current method, we compared actual Medicaid expenditures for the FUL drugs under review to the amount Medicaid would have spent had reimbursement been set at the other three pricing points.

FINDINGS

The FUL amounts calculated under the current method continue to be substantially higher than other pricing points. In the aggregate, the FUL amounts were more than four times higher than average pharmacy acquisition costs in the fourth quarter of 2007. Among individual products, the FUL amount was more than double the average pharmacy acquisition cost for 46 of the 50 highest-expenditure FUL drugs (for 24 of these, the FUL amount was at least five times higher).

In addition, aggregate FUL amounts in the fourth quarter of 2007 were almost three times higher than average Part D payment amounts. Among individual products, the FUL amount was more than double the average Part D payment amount for 335 of 572 drugs (for 51 of these, the FUL amount was at least five times higher).

Finally, in the aggregate, the FUL amounts were two times higher than prices available through retail discount generic programs in the fourth quarter of 2007. Among individual products, the FUL amount was more than double the \$4.00 retail price for a monthly supply of 129 of the 291 drugs included in these programs.

Despite the fact that States often pay less than the FUL amount for multiple-source drugs, the current calculation method is still costing Medicaid hundreds of millions of dollars per year. The FUL amounts do not always represent the actual prices paid by Medicaid, because State maximum allowable cost programs as well as usual and customary charge provisions may further lower payments for

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

multiple-source drugs. Even allowing for these reductions, average Medicaid payment amounts still exceeded the other pricing points we reviewed. As a result, if Medicaid had paid for 50 high-expenditure FUL drugs based on the average pharmacy acquisition cost, the program would have reduced expenditures by an estimated \$105 million in a single quarter (or more than \$400 million in 1 year). Similarly, if Medicaid had paid for 572 FUL drugs at the average Part D payment amount, the program would have reduced expenditures by an estimated \$138 million in a single quarter. Finally, if Medicaid had paid all pharmacies for 291 FUL drugs at the \$4.00 per 30-day price available through retail discount generic programs, the program would have reduced expenditures by an estimated \$87 million in a single quarter.

In the aggregate, AMP-based FUL amounts were much closer to other pricing points; however, for some drugs, these FUL amounts may be below acquisition costs. For the 50 FUL drugs with the highest total Medicaid expenditures, fourth-quarter 2007 AMP-based FUL amounts (not including dispensing fees) were 50 percent higher, in the aggregate, than average pharmacy acquisition costs. For 26 of these drugs, AMP-based FUL amounts were below average pharmacy acquisition costs. However, for 38 of the 50 drugs, the new FUL amounts were higher than the lowest reported acquisition costs. In other words, pharmacies would typically have been able to purchase at least one version of these drugs from a particular distributor for less than the AMP-based FUL amount. These figures do not take into account that in addition to being reimbursed by Medicaid for the cost of the drug itself (i.e., the FUL amount, the maximum allowable cost), pharmacies also receive a dispensing fee from Medicaid each time a prescription is filled.

In addition, aggregate AMP-based FUL amounts (not including dispensing fees) were 2 percent below average Part D payment amounts (not including dispensing fees) in the fourth quarter of 2007. For 337 of the 542 drugs, the AMP-based FUL amount was less than the average Part D payment.

Finally, approximately half of the drugs with an AMP-based FUL in the fourth quarter of 2007 were also included in at least one of the \$4.00 discount generic programs under review. The AMP-based FUL amounts for a 30-day supply of these same drugs averaged \$2.20, before any dispensing fees were applied. However, given that only one State had a dispensing fee that was less than \$2.00 per prescription

(New Hampshire was \$1.75), aggregate Medicaid payment amounts including the dispensing fee would still exceed the retail price under the discount programs.

RECOMMENDATION

The findings of this report demonstrate that the current method for setting FUL amounts continues to result in substantially inflated Medicaid payments for many drugs. These FULs are frequently double (and often more than five times) other prices in the marketplace. As a result, Medicaid could be overpaying by hundreds of millions of dollars per year for these drugs.

Our findings also show that AMP-based FULs calculated under the DRA-prescribed methodology significantly lessen the gap between FUL amounts and the other prices we examined. In the aggregate, the AMP-based FULs seem to cover acquisition costs, and are very similar to overall Part D reimbursement. However, despite the aggregate numbers, we have some concerns that for a number of individual drugs the AMP-based FUL amounts were substantially below average acquisition costs and Part D payment amounts.

Notwithstanding these concerns, the inflated payments resulting from the pre-DRA methodology that we observed in this review once again illustrate the flaws in the current FUL calculation. We also understand that without a legislative change and the lifting of the injunction, CMS's options are limited at this time. However, it is critical that Medicaid set payment rates that are fair and appropriate to both the government and providers. Therefore, we recommend that:

CMS should continue to work with Congress to identify strategies that would lower inflated Medicaid payments for multiple-source drugs.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation. CMS also stated that our findings support the agency's belief that AMP-based FULs more accurately reflect acquisition costs and prices used in other programs. However, the agency expressed concerns with certain aspects of our methodology.

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

Specifically, CMS stated that actual pharmacy acquisition costs are likely to be lower than the estimates used in our report because two of the four responding distributors failed to provide data on price concessions (i.e., discounts, rebates, and other price adjustments). CMS noted that our findings understate Medicaid payment rates because we did not include dispensing fees that are paid when Medicaid prescriptions are filled. The agency also noted that FULs are required to be met only in the aggregate and that States have the authority to pay more than the FUL amount for certain drugs.

OIG agrees that had all distributors included information on price concessions, our estimate of the number of drugs available at prices below the AMP-based FUL amounts may have increased. However, based on our data, this limitation does not fundamentally change the underlying issue surrounding the availability of individual drugs. In addition, because this study focused primarily on the costs of the drugs themselves, it would not have been appropriate to include dispensing fees in most pieces of our analysis. Finally, we agree that FULs apply only in the aggregate. However, it is important to balance the goal of lower aggregate payment levels with the need to ensure that FUL amounts cover acquisition costs for as many drugs as possible.

▶ **T A B L E O F C O N T E N T S**

EXECUTIVE SUMMARY i

INTRODUCTION 1

FINDINGS 16

 FUL amounts calculated under the current method continue to
 be substantially higher than other pricing points 16

 Despite the fact that States often pay less than the FUL amount
 for multiple-source drugs, the current calculation method is still
 costing Medicaid hundreds of millions of dollars per year 19

 In the aggregate, AMP-based FUL amounts were much closer to
 other pricing points; however, for some drugs, these FUL
 amounts may be below acquisition costs 22

RECOMMENDATION 26

 Agency Comments and Office of Inspector General
 Response 27

APPENDIXES 29

 A: Fifty Federal Upper Limit Drugs With Highest Total
 Medicaid Expenditures in 2007 29

 B: Agency Comments 31

ACKNOWLEDGMENTS 35

OBJECTIVES

1. To determine how Federal upper limit (FUL) amounts calculated under the current method compare to (a) pharmacy acquisition costs, (b) Medicare Part D payment amounts, and (c) retail prices under discount generic programs.
2. To estimate the financial impact on the Medicaid program of continuing to calculate FUL amounts using the current method.
3. To determine how FUL amounts calculated under the method required by the Deficit Reduction Act of 2005 (DRA) compare to the pricing points under review.

BACKGROUND

The FUL program was established to help ensure that Medicaid takes advantage of lower market prices for multiple-source drugs.¹ However, previous Office of Inspector General (OIG) work consistently found that the published prices used to set Medicaid FUL amounts often greatly exceeded prices available in the marketplace.² Based in part on this work, provisions of the DRA, P.L. No. 109-171, substantially changed the method for calculating FUL amounts. However, pharmacy groups have expressed concern that the new FUL amounts calculated under the DRA-based method may not adequately reimburse providers for their costs, thereby limiting access to certain drugs.³

In December 2007, in connection with a lawsuit filed by two trade associations representing retail pharmacies, a Federal judge issued a preliminary injunction preventing the Centers for Medicare & Medicaid Services (CMS) from using the DRA-based calculation method to change Medicaid reimbursement rates for retail pharmacies. Subsequently, section 203 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), P.L. No. 110-275, barred CMS from implementing

¹ Generally a drug is considered to be multiple-source if generic versions are available.

² "Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices," OEI-03-05-00110, June 2005.

³ See the National Association of Chain Drug Stores, "Implications of Federal Medicaid Generic Drug Payment Reductions for State Policymakers," May 2007 Issue Brief. Available online at http://www.nacds.org/user-assets/pdfs/gov_affairs/issues/Medicaid/ImplicationsFederalMedicaidGenericDrugPaymentReductionsStatePolicymakers.pdf. Accessed on April 17, 2009.

the new FUL calculation method until October 1, 2009. As of May 2009, CMS is still calculating FUL amounts using the pre-DRA methodology.

Medicaid Reimbursement for Prescription Drugs

Currently, all 50 States and the District of Columbia (hereinafter referred to as States) offer prescription drug coverage under Medicaid. In 2007, Medicaid payments for prescription drugs totaled approximately \$22 billion.⁴

Federal regulations require, with certain exceptions, that each State Medicaid agency's reimbursement for a covered outpatient drug not exceed (in the aggregate) the lower of the estimated acquisition cost plus a reasonable dispensing fee or the provider's usual and customary charge to the public for the drugs.^{5 6} CMS allows States the flexibility to define estimated acquisition cost, with most States basing their calculations on list prices published in national compendia.

For certain drugs, States also use the FUL or State maximum allowable cost programs in setting reimbursement. As of the fourth quarter of 2008, 45 States have implemented maximum allowable cost programs to limit reimbursement for certain multiple-source drugs.⁷ Individual States determine the types of drugs that are included in their maximum allowable cost program, and the methods by which the maximum allowable cost is calculated.

The FUL Program

According to CMS's Web site, the FUL 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.⁸ CMS

⁴ Calculated using national summary data for 2007. This amount includes both Federal and State payments. Rebates collected by States under the Medicaid drug rebate program were not subtracted from this figure. National and State utilization data are available online at <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/SDUD/list.asp>. Accessed on September 17, 2008.

⁵ 42 CFR § 447.512.

⁶ At the time of our review, State dispensing fees to retail pharmacies for generic drugs generally ranged from \$1.75 to \$7.25 per prescription, with fees in more than two-thirds of States falling between \$3.50 and \$5.00. Source: CMS, "Medicaid Prescription Reimbursement Information by State – Quarter Ending December 2007."

⁷ CMS, "Medicaid Prescription Reimbursement Information by State – Quarter Ending December 2008."

⁸ CMS, "Transmittal No. 37 – Federal Upper Limit Drug List," Available online at http://www.cms.hhs.gov/Reimbursement/05_FederalUpperLimits.asp. Accessed on September 17, 2008.

calculates a FUL amount for specific forms and strengths for each multiple-source drug that meets the established criteria. As of December 31, 2007, there were 576 drugs included on the FUL list. According to CMS data, these drugs accounted for 8 percent (\$1.8 billion) of Medicaid prescription drug expenditures in 2007.

Prior to the DRA, section 1927(e)(4) of the Social Security Act (the Act) and 42 CFR § 447.332 generally required CMS to establish a FUL amount for a drug when: (1) three or more formulations of the drug were rated as therapeutically equivalent by the Food and Drug Administration and (2) at least three suppliers of the drug were listed in current editions of published compendia of cost information for drugs available for sale nationally. As originally set forth in 42 CFR § 447.332, FUL amounts are equal to 150 percent of the price published in national compendia for the least costly therapeutically equivalent product that can be purchased by pharmacists in quantities of 100 tablets or capsules, plus a reasonable dispensing fee.^{9 10} States are required to meet the FUL requirements only in the aggregate, i.e., a State may pay more than the FUL amount for certain products as long as these payments are balanced out by lower payments for other products.

The most commonly used published prices in setting FULs are wholesale acquisition costs (WAC), average wholesale prices (AWP), and direct prices. National compendia, such as Redbook, publish these figures based on information provided by drug manufacturers. Although the definition of WAC is prescribed by Federal law, neither AWP nor direct price is defined in statute or regulation.¹¹

Changes to the FUL Program Under the Deficit Reduction Act of 2005

Due in part to OIG work that showed FULs based on published prices were significantly higher than other prices in the marketplace,¹² the

⁹ For liquid drugs or drugs not typically available in quantities of 100, the FUL amount is based on the price for a commonly listed size of the product.

¹⁰ 42 CFR § 447.332 has been removed, and regulatory provisions relating to FULs for multiple-source drugs are now found in 42 CFR § 447.514.

¹¹ Pursuant to section 1847A(c)(6)(B) of the Act, WAC is generally defined as the drug manufacturer's list price to wholesale distributors or direct purchasers, not including prompt pay or other discounts, rebates, or reductions in price, as reported in wholesale price guides or other publications of drug or biological pricing data.

¹² "Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices," OEI-03-05-00110, June 2005.

DRA made significant changes to the FUL program. Pursuant to section 6001(a) of the DRA, FUL amounts would be based on 250 percent of the lowest reported average manufacturer price (AMP) for each drug rather than 150 percent of the lowest price published in national compendia.

As generally defined in section 1927(k)(1) of the Act, AMP is 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. The AMP is generally calculated as a weighted average of prices for a manufacturer's package sizes of a drug sold during a given quarter and is reported for the lowest identifiable quantity of the drug. Prior to the passage of the DRA, section 1927(b)(3) of the Act required manufacturers to provide CMS with the AMP for each of their covered drugs on a quarterly basis, with submissions due 30 days after the close of each quarter. Under the DRA provisions, manufacturers must also report AMPs on a monthly basis, with submissions due 30 days after the end of each month.¹³ The DRA provisions require CMS to disclose AMP data to both States and the public, thereby allowing States the option of using the AMP when setting reimbursement rates for covered drugs.¹⁴

The DRA also expanded the criteria for including a drug in the FUL program. Pursuant to section 6001(a) of the DRA, for a FUL to be set for a drug, only two therapeutically equivalent versions are required.

Implementation of FUL Amounts Based on AMPs

In July 2007, CMS published a final rule that among other things, implemented the DRA provisions related to FULs.¹⁵ For example, 42 CFR § 447.504 of the 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 FUL amounts. Pursuant to 42 CFR § 447.514(c), CMS will exclude the lowest AMP from the FUL calculation if it is an outlier. CMS defines an outlier as a lowest AMP that is less than 40 percent of the second-lowest AMP (i.e., a lowest AMP that is more than 60 percent below the second lowest AMP), with

¹³ DRA, § 6001(b)(1)(A).

¹⁴ DRA, § 6001(b). Prior to the DRA, section 1927(b)(3)(D) of the Act guaranteed the confidentiality of AMP data reported by manufacturers (with certain exceptions).

¹⁵ 72 Fed. Reg. 39142, 39244 (July 17, 2007).

certain exceptions.¹⁶ According to CMS, the outlier policy is designed to help ensure that two or more drug products can be purchased at or below the FUL amount.¹⁷

In addition, in the preamble to the regulation, CMS explained that it intends to use monthly AMPs when calculating FUL amounts.¹⁸ The monthly AMP-based FULs will represent transactions that occurred 3 months previously.¹⁹ For example, had the new DRA requirements been in effect during December 2008, FULs published for that month would have been based on AMPs submitted by manufacturers for sales in September 2008.

Although the final regulation took effect on October 1, 2007, CMS has yet to use AMP data when establishing FUL amounts (as of August 2009). Initially, CMS planned to issue the first AMP-based FULs on December 30, 2007.²⁰ However, on December 19, 2007, the U.S. District Court for the District of Columbia issued a preliminary injunction which prevented CMS from implementing its final rule concerning AMPs to the extent that the rule affects Medicaid reimbursement rates for retail pharmacies. In July 2008, the MIPPA further delayed the implementation of new FULs based on AMPs. Consistent with sections 203(a) and (b) of the MIPPA, CMS must not take action to implement AMP-based FUL amounts or publicly disclose AMP data before October 1, 2009. Until at least that time, AMPs will not be publicly disclosed and FUL amounts will continue to be calculated using the pre-DRA methodology, i.e., 150 percent of the lowest published price.²¹ In addition, as of August 2009, CMS has not yet implemented the expanded DRA criteria for including multiple-source drugs on the FUL list.

Pharmacy Acquisition of Prescription Drugs

In most cases, Medicaid beneficiaries obtain covered drugs from pharmacies. Pharmacies typically purchase drugs through wholesale

¹⁶ Pursuant to 42 CFR § 447.514(c)(3), the outlier policy will not apply when the FUL group includes only the brand name drug and the first new generic or authorized generic drug that has entered the market.

¹⁷ 72 Fed. Reg. 39142, 39216 (July 17, 2007).

¹⁸ 72 Fed. Reg. 39142, 39207 (July 17, 2007).

¹⁹ CMS, "Average Manufacturer Price/Federal Upper Limits Timeline."

²⁰ *Ibid.*

²¹ MIPPA, §§ 203(a) and (b).

distributors or directly from manufacturers. According to industry reports, three companies (AmeriSource Bergen, Cardinal Health, and McKesson) account for between 90 percent and 95 percent of the drug wholesale distributor market share, and four out of every five drugs sold in the United States are obtained through one of these three companies.²²

Medicare Part D Payment for Prescription Drugs

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, established Medicare Part D to provide prescription drug coverage to Medicare beneficiaries. While Medicaid is administered by State Medicaid agencies, CMS contracts with private companies to administer Part D prescription drug plans.

Pharmacy reimbursement under Medicare Part D is based, in part, on negotiated prices. CMS defines negotiated prices (or point-of-sale prices) as prices for covered Part D drugs that: (1) are available to beneficiaries at the point of sale at network pharmacies; (2) are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and (3) include any pharmacy dispensing fees.²³ Negotiated prices are typically based on agreements between manufacturers, plan sponsors, and affiliated contractors (e.g., pharmacy benefit managers). Although negotiated prices are a basis for pharmacy reimbursement, they do not reflect all costs to the Government for Part D.²⁴

Medicare beneficiaries typically obtain prescription drugs from pharmacies, which contract with Part D sponsors to obtain reimbursement for these drugs. According to CMS staff, negotiated

²² “Growing Share of ‘Big Three’ Gets Federal Attention.” Market Watch. May 30, 2007. Available online at <http://www.marketwatch.com/news/story/growing-share-big-three-drug/story.aspx?guid=%7B9F3862C1-7E3A-4D82-94B7-A8E4AE5DAE6A%7D>. Accessed on April 7, 2009.

²³ Ibid.

²⁴ The program costs of Medicare Part D are determined by plan bids and reconciliation payments. Once a year, each plan sponsor submits a bid, which is an estimate of the average cost to provide the basic benefit per beneficiary. Throughout the year, CMS makes prospective payments to sponsors for three subsidies based on sponsors’ approved bids. These subsidies are: (1) the direct subsidy, (2) the reinsurance subsidy, and (3) the low-income cost-sharing subsidy. Plan sponsors and CMS then reconcile actual costs and prospective payments at the end of the year. Source: CMS, “2006 Prescription Drug Event Data Training Participant Guide.”

prices used for pharmacy reimbursement are usually based on the AWP discounted by a specified percentage or maximum allowable cost plus a dispensing fee.

Retail Chain Generic Prescription Drug Programs

Several large retail chain stores sponsor prescription drug programs where a selected number of multiple-source drugs are sold at a set price. For example, as of March 2009, Wal-Mart offers more than 300 different multiple-source drugs at \$4.00 for a 30-day supply and \$10 for a 90-day supply. Similarly, other retail chains have comparable plans that offer 30-day or 90-day supplies of multiple-source drugs for prices similar to Wal-Mart.²⁵ Many of the drugs offered by these chains are covered by Medicaid's FUL program.

Based on Medicaid's usual and customary charge provisions, if a beneficiary obtains a drug through one of these retail generic programs, the program should generally reimburse the pharmacy at the discounted price, i.e., \$4.00 for the 30-day supply (assuming that price is lower than the FUL amount, maximum allowable cost, etc.).²⁶ In these cases, Medicaid would not pay an additional dispensing fee to the pharmacy because the \$4.00 amount represents the total charge associated with the beneficiary's receipt of the drug.

Previous OIG Work on the FUL Program

In our June 2005 report, "Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices" (OEI-03-05-00110), we found that FUL amounts were five times higher than average AMPs. At that time, we recommended that CMS work with Congress to set FUL amounts that more closely approximate pharmacy acquisition costs.

In June 2007, OIG released a report assessing the potential effect of AMP-based FULs entitled "Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program" (OEI-03-06-00400). We found that pre-DRA FUL amounts substantially exceeded estimated average pharmacy acquisition costs for 25 selected drugs in the second quarter of 2006, but would decrease considerably under the new calculation

²⁵ At the time of our review, other retail chains with \$4.00/30-day discount prescription drug programs included Kroger, Target, Safeway, Delhaize, Basha's, and Giant Eagle. Several other companies offered similar programs for 90-day supplies only.

²⁶ If the pharmacy charges a fee to join their discount generic program, CMS does not have a stated policy as to whether the prices charged under that program would meet the definition of a usual and customary charge to the public.

method established by the DRA. In fact, pharmacies would only have been able to purchase 6 of the 25 reviewed drugs for less than the new FUL amount, on average.²⁷ We recommended that CMS take steps to identify when a new FUL amount was not representative of a drug's acquisition cost, and in these cases, determine a proper course of action.

In OIG's February 2009 report, "Comparing Pharmacy Reimbursement: Medicare Part D to Medicaid" (OEI-03-07-00350), we found that the average Medicaid pharmacy reimbursement amounts typically exceeded the average Part D reimbursement amounts for selected multiple-source drugs. Specifically, for the 14 FUL drugs included in that review, the average Medicaid reimbursement amount for all but one exceeded the average Part D reimbursement amount. At the median, the Medicaid reimbursement amount was 32 percent greater than the Part D reimbursement amount for these 14 drugs. In addition, we found that Medicaid dispensing fees in the five States under review exceeded average Part D dispensing fees for multiple-source drugs by at least 55 percent.

METHODOLOGY

Scope

This study compared the FUL amounts calculated under both the current pre-DRA method and the AMP-based method to several pricing points:

1. estimated fourth-quarter 2007 pharmacy acquisition costs for the 50 FUL drugs with the highest total Medicaid expenditures in 2007,
2. average Part D pharmacy payment amounts for nearly all FUL drugs in the fourth quarter of 2007, and
3. retail pricing for any FUL drugs included in selected companies' discount generic programs.

The 50 drugs in the first comparison accounted for 52 percent (\$941 million) of total Medicaid expenditures for the FUL drugs in 2007.

²⁷ At the time OIG conducted its assessment, CMS had not fully developed its outlier policy. Therefore, for the purposes of that report, the FUL amounts were calculated without regard to outlier AMPs.

Because many States pay less than the FUL amount for drugs through maximum allowable cost programs and usual and customary charge provisions, we also calculated average Medicaid payment amounts for each drug on the FUL list in the fourth quarter of 2007. We compared the average Medicaid payment amounts to each of the three pricing points described above.

We estimated pharmacy acquisition costs for the fourth quarter of 2007 based on information obtained from wholesale distributors of prescription drugs. Responding distributors represent approximately 90 percent to 95 percent of the pharmaceutical distribution industry's market share and revenue. We limited our analysis of retail chain discount pricing to 30-day supplies of drugs, although some programs did offer 90-day supplies for a lower per-unit price.

To estimate the financial impact of continuing to base the FUL amounts on the current method, we compared actual Medicaid expenditures for the FUL drugs under review to the amount Medicaid would have spent had reimbursement been set at the other three pricing points.

FUL Amounts and Medicaid Payments

Current FUL amounts. Using information in the drug compendium Redbook, we obtained CMS-calculated FUL amounts for all 576 drugs included on the FUL list in the fourth quarter of 2007. We verified the Redbook information by comparing drug name and FUL amount data to the FUL listings on CMS's Web site.

AMP-based FUL amounts. We also obtained from CMS a file listing the December 2007 FUL amounts as calculated under the unimplemented DRA methodology (i.e., 250 percent of the lowest AMP). Although CMS is currently prohibited from reimbursing based on this method, the agency is still calculating AMP-based FUL amounts for internal use. CMS applied its outlier policy when determining these FUL amounts. CMS had calculated AMP-based FULs for 542 of the 576 drugs included on the FUL list in the fourth quarter of 2007.²⁸

Average Medicaid payment amounts. We obtained the 2007 Medicaid drug utilization file from CMS's Web site. This file provides the total Medicaid expenditures (ingredient costs and dispensing fees), the total

²⁸ Under the expanded DRA criteria, CMS has calculated AMP-based FUL amounts for a total of 1,207 drugs.

number of prescriptions, and the total number of units dispensed by each State for prescription drugs in each quarter of 2007. Using this data, we calculated an average Medicaid payment per unit in the fourth quarter of 2007 for each drug on the FUL list by dividing the total expenditures by the total units. Because the total expenditure data includes a dispensing fee, we also calculated a second average Medicaid payment for the ingredient cost portion only.²⁹

Pharmacy Acquisition Costs

Determining pharmacy acquisition costs. Using data from the Medicaid drug utilization file, we identified the 50 FUL drugs with the highest total Medicaid expenditures in 2007 (please refer to Appendix A for a list of the 50 drugs). We sent data requests for fourth-quarter 2007 pricing and sales data to the three largest national distributors (AmerisourceBergen, McKesson, and Cardinal Health) 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 any price concessions (e.g., discounts, rebates, and other price adjustments) paid to purchasers; the net dollar amount sold; the total number of units sold; and the average selling price during the fourth quarter of 2007 for all national drug codes associated with the 50 highest-expenditure FUL drugs.³⁰

Four of the five distributors (three national and one regional) responded to our request in time for their cost data to be included. Because of the highly sensitive nature of the data, we are not listing average acquisition costs for individual FUL drugs. Only two of the four distributors provided information on price concessions.

To estimate average pharmacy acquisition costs per unit for each of the 50 selected highest-expenditure drugs, we totaled the dollar amount sold (net of any price concessions, when provided) by the four

²⁹ We could only calculate this cost for States that had relatively simple formulas for determining the dispensing fees paid to retail pharmacies (e.g., \$4.00 per generic prescription). For the 45 States that had a relatively simple dispensing fee, we calculated the unit Medicaid ingredient cost for each drug by subtracting the total dispensing fees paid from total expenditures in the fourth quarter of 2007. To calculate total dispensing fees, we multiplied the State's dispensing fee from the fourth quarter of 2007 by the total number of prescriptions for each drug. For each FUL drug, we then divided the total ingredient costs by the total number of units dispensed.

³⁰ National drug codes are unique 11-digit identifiers that indicate the manufacturer, product dosage form, and package size of a drug.

responding 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 unit price reported to OIG by the distributors for any version (i.e., national drug code) of each drug.

Comparing pharmacy acquisition costs to Medicaid. For each of the 50 drugs, we compared the average pharmacy acquisition costs to the current FULs, AMP-based FULs, and average Medicaid payment amounts. We also compared the AMP-based FULs to the lowest costs reported by the distributors. Because FULs apply in the aggregate, we also determined an overall difference between acquisition costs and the two FUL amounts. To calculate aggregate differences, we determined how much Medicaid would have spent for each drug if it had paid at acquisition cost by multiplying the acquisition cost by the number of units of the drug reimbursed by Medicaid in the fourth quarter of 2007. We compared the result to potential spending under the pre-DRA and AMP-based FUL methodologies (which were calculated using the same method—FUL amounts multiplied by Medicaid fourth-quarter 2007 utilization). All the comparisons described above only addressed the ingredient cost of the drugs and not any dispensing fees.

Estimating potential costs. We estimated the potential costs to Medicaid of continuing to use the current calculation method in setting the FUL amounts by comparing the total amount Medicaid actually spent on the FUL drugs under review in the fourth quarter of 2007 (net of dispensing fees) to aggregate spending had reimbursement been set at the average pharmacy acquisition cost.

Medicare Part D Payment Amounts

Determining Part D payment amounts. For all drugs included in the FUL program, we obtained fourth-quarter 2007 prescription drug event (PDE) records from CMS. A PDE record contains the ingredient cost and the dispensing fee paid to the pharmacy for each claim. In the fourth quarter of 2007, 572 of the 576 drugs on the FUL list had been reimbursed under Part D.³¹ To determine the average Part D payment amount per unit for each FUL drug, we totaled the dollar amount reimbursed for the ingredient cost portion and divided this amount by the number of units reimbursed.

³¹ All 542 drugs with AMP-based FULs had Part D reimbursement that quarter.

Comparing Part D payment amounts to Medicaid. We then compared the average Part D payment amounts to the current FULs, AMP-based FULs, and average Medicaid payment amounts for each of the drugs. Because FULs apply in the aggregate, we also determined an overall difference between Part D payment amounts and the two FUL amounts. To calculate aggregate differences, we determined how much Medicaid would have spent for each drug if it had paid at the average Part D amount by multiplying the Part D payment amount by the number of units of the drug reimbursed by Medicaid in the fourth quarter of 2007. We compared the result to potential spending under the pre-DRA and AMP-based FUL methodologies (which were calculated using the same method—FUL amounts multiplied by Medicaid fourth-quarter 2007 utilization). All the comparisons described above only addressed the ingredient cost of the drugs and not any dispensing fees.

Estimating potential costs. We estimated the potential costs to Medicaid of continuing to use the current calculation method in setting the FUL amounts by comparing the total amount Medicaid actually spent on the FUL drugs under review in the fourth quarter of 2007 (net of dispensing fees) to aggregate spending had reimbursement been set at the Part D payment amount.

Prices Under Retail Generic Programs

Determining drugs included in programs. We selected seven retail chain pharmacies that offered a \$4.00/30-day discount generic program: WalMart, Target, Safeway, GiantEagle, Kroger, Basha's, and Delhaize.³² From each chain company's Web site, we obtained information on each program including a list of the covered drugs and the quantity dispensed for a 30-day supply.³³ In total, 291 FUL drugs were included in at least one company's discount generic program.³⁴ The prices offered by these programs are the final cost for the drugs, i.e., no additional dispensing fee is paid by the customer/payor.

Comparing retail prices to Medicaid. The price for all 291 drugs included in the selected retail discount generic programs was \$4.00 for a 30-day

³² Basha's actually charged \$3.99 per month. For analysis purposes, we rounded this amount to \$4.00

³³ Discount generic program information was obtained from company Web sites during the third and fourth quarters of 2008. We could not determine whether any of the drugs included in these programs had changed since the fourth quarter of 2007.

³⁴ CMS had calculated AMP-based FULs for 279 of these 291 drugs.

supply. In comparing FULs to retail generic programs, we based our calculations on a 30-day cost of the drugs rather than per-unit prices. To determine the corresponding FUL amount for a 30-day supply for each of the 291 drugs included in at least one discount generic program, we multiplied the per-unit FUL amount by the number of units in a 30-day supply of the drugs.³⁵ We compared the results to the \$4.00 prices offered under the discount generic programs.

Because FULs apply in the aggregate, we also determined an overall difference between retail prices and the two FUL amounts. To calculate aggregate differences, we determined how much Medicaid would have spent for each drug if it had paid all pharmacies at the price available through the retail generic programs by multiplying the \$4.00 retail price by the number of “30-day supplies” of the drug reimbursed by Medicaid in the fourth quarter of 2007. We compared the result to potential spending under the pre-DRA and AMP-based FUL methodologies (which were calculated using the same method—FUL amounts multiplied by Medicaid fourth-quarter 2007 utilization). Because the retail prices under these programs are the total prices paid, the comparisons described above would underestimate actual price differences given that the FUL amounts represent ingredient costs only and do not include dispensing fees.

Estimating potential costs. We estimated the potential costs to Medicaid of continuing to use the current calculation method in setting the FUL amounts by comparing the total amount Medicaid actually spent on the FUL drugs under review in the fourth quarter of 2007 to aggregate spending at these retail prices. Because we were able to include dispensing fees in this particular comparison (i.e., the total Medicaid expenditures used in this calculation included dispensing fees), the potential costs figure is based on total costs under both pricing points, and does not underestimate potential program savings.

Tables 1 and 2 in the next page summarize the number of drugs used in each comparison and whether or not dispensing fees were included in the analysis.

³⁵ For 47 drugs, the number of units (e.g., pills), in a 30-day supply was not identical for each company. To be conservative, in analyzing costs for these drugs, we used the lowest number of units listed by any company.

I N T R O D U C T I O N

Table 1: Number of Drugs Included in Each Comparison

Method	Average Acquisition Cost	Medicare Part D Payment Amounts	Retail Discount Generic Program Prices
Current FUL	50	572	291
AMP-Based FUL	50	542	279

Table 2: Inclusion of Dispensing Fee in Analysis

Method	Average Acquisition Cost	Medicare Part D Payment Amounts	Retail Discount Generic Program Prices
Current FUL	Ingredient Cost Only	Ingredient Cost Only	FUL is Ingredient Cost Only Retail is Total Cost
AMP-Based FUL	Ingredient Cost Only	Ingredient Cost Only	FUL is Ingredient Cost Only Retail is Total Cost
Average Medicaid Cost/Savings	Ingredient Cost Only	Ingredient Cost Only	Total Cost (Ingredient Cost and Dispensing Fee)

Limitations

Our analysis is limited to drugs listed by CMS as being included in the FUL program in the fourth quarter of 2007. CMS has not yet implemented the DRA’s expanded criteria (i.e., two therapeutically equivalent versions instead of the current three therapeutically equivalent versions).

For both the pre-DRA and AMP-based FULs, we used the amounts calculated by CMS. We did not verify that pre-DRA FUL amounts were actually set at 150 percent of the lowest published price, or that the AMP-based FULs were set at 250 percent of the lowest AMP (excluding outliers).

Four of the five distributors responded to our data request in time to be included in the analysis. Two of the four responding distributors did not provide data on price concessions. Therefore, pharmacies’ bottom-line costs for some drugs may be lower than the estimates used in the report. In addition, we did not determine whether the prices reported by the distributors were nationally available to all pharmacies.

I N T R O D U C T I O N

The percentage differences between FULs and other pricing points are limited to the drugs included in each comparison, and are not projectable to all drugs covered under the Medicaid FUL program.

We did not verify the accuracy or completeness of sales data from wholesalers used to estimate pharmacy acquisition costs, PDE data, or data received from retail chain pharmacies' Web sites. In addition, we analyzed Medicaid utilization data summarized by drug, i.e., we did not analyze claims-level data.

We did not verify whether drugs purchased at pharmacies with discount generic programs were billed and reimbursed at the usual and customary charge (i.e., \$4.00) rather than the FUL amount or State maximum allowable cost plus a dispensing fee.

We did not include rebates available to States through the Medicaid drug rebate program or any post-point-of-sale price concessions available to Part D plan sponsors, pharmacies, or beneficiaries in this analysis.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" approved by the Council of the Inspectors General on Integrity and Efficiency.

► FINDINGS

FUL amounts calculated under the current method continue to be substantially higher than other pricing points

Consistent with previous OIG findings, the FUL amounts under the pre-DRA methodology (i.e., 150 percent of the lowest published price) substantially

exceeded other prices in the marketplace. In the fourth quarter of 2007, the FUL amounts, both in the aggregate and for many individual drugs, were often several times higher than average pharmacy acquisition costs, Part D payment amounts, and retail generic program prices.

In the aggregate, FUL amounts calculated under the current methodology were more than four times higher than average pharmacy acquisition costs in the fourth quarter of 2007

For the 50 FUL drugs with the highest total Medicaid expenditures, fourth-quarter 2007 FUL amounts were 4.32 times higher, in the aggregate, than average pharmacy acquisition costs. This figure does not take into account that in addition to being reimbursed by Medicaid for the cost of the drug itself (i.e., the FUL amount, the maximum allowable cost), pharmacies usually receive a dispensing fee from Medicaid each time a prescription is filled.³⁶

Among individual products, 47 of the 50 drugs under review had FUL amounts that exceeded average pharmacy acquisition costs. In all but one of these cases, the FUL amounts were more than double average pharmacy acquisition costs. For almost half of the drugs under review (24 of 50), the FUL amount was at least five times greater than the average pharmacy acquisition cost. For example, pharmacies were able to purchase Gabapentin 300 milligrams (mg) (the product with the second-highest total Medicaid payments among FUL drugs) for an average of \$0.08 per capsule in the fourth quarter of 2007; at that time, the FUL amount was \$1.31 per capsule. Table 3 provides a summary of the difference between the FUL amounts and the average pharmacy acquisition costs in the fourth quarter of 2007 for the drugs under review.

Actual dollar differences between the FUL amounts and the average pharmacy acquisition costs varied substantially, depending on a drug's cost and the amount of a drug represented by one unit (e.g., 1 tablet,

³⁶ Pharmacies would not receive a dispensing fee if they were reimbursed at their usual and customary charge rather than the FUL or the maximum allowable cost.

FINDINGS

1 milliliter of liquid, 1 gram of cream). Differences ranged from \$0.02 to \$6.08 per unit, with 32 of the 50 drugs having a unit price difference of less than \$0.50.

Table 3: Comparison of Pre-DRA FUL Amounts to Average Pharmacy Acquisition Costs in the Fourth Quarter of 2007

Difference	Number of Drugs	Percentage of Drugs
FUL amount less than average pharmacy acquisition cost	3	6 percent
FUL amount between 0.01 and 2 times higher than average pharmacy acquisition cost	1	2 percent
FUL amount between 2.01 and 5 times higher than average pharmacy acquisition cost	22	44 percent
FUL amount between 5.01 and 10 times higher than average pharmacy acquisition cost	10	20 percent
FUL amount more than 10 times higher than average pharmacy acquisition cost	14	28 percent
Total Drugs	50	100 percent
Aggregate Amount Higher Than Average Pharmacy Acquisition Cost	4.32 times	

Source: OIG analysis of CMS FUL Data and Distributor Sales Data.

In the aggregate, the FUL amounts calculated under the current methodology were almost three times higher than average Part D payment amounts in the fourth quarter of 2007

Fourth-quarter 2007 FUL amounts were 2.91 times higher, in the aggregate, than average Part D payment amounts. This figure does not take into account that both Medicaid and Part D usually pay a dispensing fee in addition to the ingredient cost payment.³⁷

Among individual products, the FUL amount was higher than the average Part D payment for 546 out of the 572 drugs reviewed (95 percent). In 335 cases (59 percent), the FUL amount was more than double the Part D payment, and for 51 of these, the FUL amount was at least five times higher. Table 4 provides a summary of the difference between the FUL amounts and the average Part D payment amounts in the fourth quarter of 2007 for the drugs under review.

³⁷ As previously stated, in a February 2009 OIG report (OEI-03-07-00350), we found that Medicaid dispensing fees in the five States under review exceeded Part D dispensing fees for multiple-source drugs by at least 55 percent.

F I N D I N G S

Actual dollar differences ranged from less than \$0.01 to \$6.98 per unit, with 434 of the 572 drugs having a unit price difference of less than \$0.50.

Table 4: Comparison of Pre-DRA FUL Amounts to Average Part D Payment Amounts in the Fourth Quarter of 2007		
Difference	Number of Drugs	Percentage of Drugs
FUL amount less than average Part D payment amount	26	5 percent
FUL amount between .01 and 2 times higher than average Part D payment amount	211	37 percent
FUL amount between 2.01 and 5 times higher than average Part D payment amount	284	50 percent
FUL amount between 5.01 and 10 times higher than average Part D payment amount	46	8 percent
FUL amount more than 10 times higher than average Part D payment amount	5	1 percent
Total Drugs	572	100 percent*
Aggregate Amount Higher Than Average Part D Payment Amount	2.91 times	

* Individual totals displayed in table do not add up to 100 percent because of rounding.

Source: OIG analysis of CMS FUL Data and Retail Chain Pricing.

In the aggregate, the FUL amounts calculated under the current methodology were double the prices available through retail discount generic programs

Fourth-quarter 2007 FUL amounts were 1.97 times higher, in the aggregate, than prices available through retail discount generic programs. Approximately half (291) of the drugs included on the FUL list in the fourth quarter of 2007 were also included in at least one of the discount generic programs under review.³⁸ Under the discount programs, each of these drugs had a retail price of \$4.00 for a 30-day supply (total cost to the consumer). In the aggregate, the FUL amounts for a 30-day supply of these same drugs averaged \$7.87 before any dispensing fees were applied.³⁹

³⁸ However, only 18 of the 50 FUL drugs with the highest total Medicaid expenditures were included in at least one discount program.

³⁹ As previously stated, the majority of States have dispensing fees between \$3.50 and \$5.00 per prescription.

FINDINGS

Among individual products, 212 of the 291 drugs had monthly FUL amounts that were above the \$4.00 retail price, with 129 exceeding \$8.00 (see Table 5). For Fluoxetine 40 mg capsules, the FUL amount for a 30-day supply was \$120, or 30 times higher than the retail price.

Table 5: Comparison of Pre-DRA FUL Amounts to Retail Prices Under \$4.00/30-day Discount Generic Programs

Difference	Number of Drugs	Percentage of Drugs
FUL amount for 30-day supply less than or equal to \$4.00	79	27 percent
FUL amount for 30-day supply between \$4.01 and \$8.00	83	29 percent
FUL amount for 30-day supply between \$8.01 and \$20.00	94	32 percent
FUL amount for 30-day supply between \$20.01 and \$100.00	29	10 percent
FUL amount for 30-day supply more than \$100.00	6	2 percent
Total Drugs	291	100 percent
Aggregate Retail Price for 30-Day Supply	\$7.87	

* \$4.00 retail prices represent a total cost. The FUL amount only represents the ingredient cost for the drug. Pharmacies without discount generic programs usually would also receive a dispensing fee in addition to reimbursement for the ingredient cost portion.

Source: OIG analysis of CMS FUL Data and PDE Data.

Despite the fact that States often pay less than the FUL amount for multiple-source drugs, the current calculation method is still costing Medicaid hundreds of millions of dollars per year

The FUL amounts do not always represent the actual prices paid by Medicaid, because State maximum allowable cost programs as well as usual and customary charge provisions may further lower payments for multiple-source drugs.

In other words, the percentage differences described in the previous finding, while accurate in relation to the FUL amounts, may overstate actual differences between Medicaid payments and these other pricing points in practice. However, even allowing for this fact, average Medicaid payment amounts still exceeded the other pricing points we reviewed by a substantial margin, potentially costing the program hundreds of millions of dollars per year.

If Medicaid had paid for 50 FUL drugs based on the average pharmacy acquisition cost, the program would have reduced expenditures by \$105 million in a single quarter

Even considering payment reductions under maximum allowable cost programs or usual and customary charge provisions, States still paid, in the aggregate, an estimated 2.7 times more than the average pharmacy acquisition cost for the 50 high-expenditure drugs under review (compared to 4.32 times had States actually paid at the FUL amounts). Furthermore, this does not take into account that pharmacies usually receive a dispensing fee each time a drug is dispensed, meaning that the gap between Medicaid payment and pharmacy cost is wider than described.

Medicaid would have spent an estimated \$105 million less in the fourth quarter of 2007 on the 50 drugs under review had States paid at the average pharmacy acquisition cost.⁴⁰ Assuming pricing and utilization was constant across all quarters of 2007, Medicaid expenditures for these 50 drugs could have been reduced by more than \$400 million over the entire year (see Table 6).

If Medicaid had paid for 572 FUL drugs at the average Part D payment amount, the program would have reduced expenditures by \$138 million in a single quarter

Even considering payment reductions under maximum allowable cost programs or usual and customary charge provisions, States still paid, in the aggregate, an estimated 84 percent more than Part D for the 572 drugs under review (compared to 191 percent more had States actually paid at the FUL amounts).⁴¹ Medicaid would have spent an estimated \$138 million less in the fourth quarter of 2007 on the FUL drugs had States paid the same as Part D. Assuming pricing and utilization was constant across all quarters of 2007, Medicaid expenditures for these 572 drugs could have been reduced by more than \$500 million over the entire year.

⁴⁰ If States chose to raise dispensing fees to offset lower ingredient cost payments, these savings would be reduced.

⁴¹ This does not take dispensing fees into account. Given that Medicaid tends to pay higher dispensing fees than Part D, the difference in reimbursement between Medicaid and Medicare Part D is likely greater than the estimated 84 percent.

F I N D I N G S

If Medicaid had paid all pharmacies for 291 FUL drugs at the price available through retail discount generic programs, the program would have reduced expenditures by \$87 million in a single quarter

States paid, in the aggregate, an estimated two times more than retail prices for the 291 drugs included in discount generic programs. The average Medicaid payment amount for a 30-day supply of these drugs was \$8.01, including dispensing fee. Each drug could be purchased for a total cost of \$4.00 at one or more of the retail chain pharmacies included in our review.

Medicaid would have spent an estimated \$87 million less in the fourth quarter of 2007 on these drugs had States paid all pharmacies at the \$4.00/30-day price. Assuming pricing and utilization was constant across all quarters of 2007, Medicaid expenditures for these 291 FUL drugs could have been reduced by almost \$350 million over the entire year.

It is important to note that if a Medicaid beneficiary obtained any of these 291 drugs from a pharmacy with a discount generic program, usual and customary charge provisions would generally apply. In other words, Medicaid should (and may) have reimbursed the pharmacy no more than a total of \$4.00 total for the drug, with no additional dispensing fee applied.

Table 6: Potential Costs to Medicaid of Current FUL Methodology in the Fourth Quarter of 2007

	Average Pharmacy Acquisition Costs*	Average Part D Payment Amounts*	Retail Discount Generic Program Prices
Number of drugs	50	572	291
Actual fourth quarter 2007 Medicaid payments under pre-DRA method	\$167.7 million	\$301.3 million	\$174.5 million
Estimated fourth quarter 2007 Medicaid payments under other pricing point	\$62.8 million	\$163.7 million	\$87.1 million
Difference (estimated quarterly savings)	\$104.9 million	\$137.6 million	\$87.4 million

*Figures for the pharmacy and Part D comparisons are based only on the ingredient cost portion of total Medicaid payments, and do not reflect dispensing fees.

Source: OIG analysis of CMS FUL Data and Utilization Data, Distributor Sales Data, PDE Data, and Retail Chain Pricing.

In the aggregate, AMP-based FUL amounts were much closer to other pricing points; however, for some drugs, these FUL amounts may be below acquisition costs

In the fourth quarter of 2007, the FUL amounts calculated under the DRA-mandated method (i.e., 250 percent of the lowest

AMP) were, in the aggregate, 66 percent below the FUL amounts based on published prices, and 47 percent below the average Medicaid payment amounts.⁴² Taken as a whole, these AMP-based FUL amounts were much closer to pharmacy acquisition costs, Part D payment amounts, and retail generic program prices. However, for a number of individual drugs, the DRA-based changes to the calculation methodology led to FUL amounts that were substantially below these other pricing points.

In the aggregate, AMP-based FUL amounts were 50 percent higher than average pharmacy acquisition costs in the fourth quarter of 2007; however, the FUL amounts for a number of drugs were less than acquisition costs

For the 50 FUL drugs with the highest total Medicaid expenditures, fourth-quarter 2007 AMP-based FUL amounts were 50 percent higher, in the aggregate, than average pharmacy acquisition costs. This figure does not take into account that in addition to being reimbursed by Medicaid for the cost of the drug itself (i.e., the FUL amount, the maximum allowable cost), pharmacies usually receive a dispensing fee from Medicaid each time a prescription is filled.

Among individual products, fourth-quarter 2007 AMP-based FUL amounts were less than average pharmacy acquisition costs for 26 of the 50 drugs under review. In eight cases, the FUL amount was less than half of the average acquisition cost, meaning pharmacies could pay much more than the new payment limit when acquiring these drugs.

In contrast, 24 of the 50 drugs had AMP-based FUL amounts that exceeded average acquisition costs, including 6 of the 7 FUL drugs with the highest Medicaid expenditures in 2007. Eight drugs had AMP-based FUL amounts that were still more than double their average acquisition costs. Table 7 provides a summary of the difference between AMP-based FUL amounts and average pharmacy acquisition costs in the fourth quarter of 2007 for the drugs under review.

⁴² Taking into account what Medicaid actually paid for the drugs, aggregate spending would have been \$140 million less under the AMP-based calculation method that quarter.

F I N D I N G S

Table 7: Comparison of AMP-Based FUL Amounts to Average Pharmacy Acquisition Costs in the Fourth Quarter of 2007

Percentage Difference	Number of Drugs	Percentage of Drugs
FUL amount more than 80 percent below average pharmacy acquisition cost	2	4 percent
FUL amount between 50.01 and 80 percent below average pharmacy acquisition cost	6	12 percent
FUL amount between 20.01 and 50 percent below average pharmacy acquisition cost	11	22 percent
FUL amount between 0.01 and 20 percent below average pharmacy acquisition cost	7	14 percent
FUL amount equal to average pharmacy acquisition cost	0	0 percent
FUL amount between 0.01 and 20 percent above average pharmacy acquisition cost	2	4 percent
FUL amount between 20.01 and 50 percent above average pharmacy acquisition cost	6	12 percent
FUL amount between 50.01 and 100 percent above average pharmacy acquisition cost	8	16 percent
FUL amount more than 100 percent above average pharmacy acquisition cost	8	16 percent
Total Drugs	50	100 percent

Source: OIG analysis of CMS FUL Data and Distributor Sales Data.

We also examined the lowest average costs reported by any wholesale distributor for any single version (i.e., national drug code) of a FUL drug. In the aggregate, AMP-based FUL amounts were more than double the lowest acquisition costs. For 38 of the 50 drugs, the AMP-based FUL amounts were higher than the lowest costs reported by wholesale distributors. In other words, pharmacies may have been able to purchase these versions from a particular distributor for less than the AMP-based FUL amount.

In the aggregate, AMP-based FUL amounts were 2 percent below average Part D payment amounts in the fourth quarter of 2007

For the 542 drugs included in this portion of the analysis, fourth-quarter 2007 AMP-based FUL amounts were 2 percent below average Part D payment amounts, in the aggregate. This figure does not take into account that both Medicaid and Part D usually pay a dispensing fee in addition to the ingredient cost payment. Given that Medicaid tends to pay higher dispensing fees than Part D, State payments to pharmacies under the AMP-based FULs may actually exceed Part D payments (in the aggregate) once dispensing fees are considered.

F I N D I N G S

Among individual products, the AMP-based FUL amount was less than the average Part D payment amount for 337 of 542 drugs (62 percent) (see Table 8). The FUL amount was less than half of the Part D payment in 161 of these cases. In contrast, the AMP-based FUL amount was more than double the Part D payment for 50 of the 542 drugs.

Table 8: Comparison of AMP-Based FUL Amounts to Average Part D Payment Amounts in the Fourth Quarter of 2007

Percentage Difference	Number of Drugs	Percentage of Drugs
FUL amount more than 80 percent below average Part D payment amount	34	6 percent
FUL amount between 50.01 and 80 percent below average Part D payment amount	127	23 percent
FUL amount between 20.01 and 50 percent below average Part D payment amount	103	19 percent
FUL amount between .01 and 20 percent below average Part D payment amount	73	13 percent
FUL amount equal to average Part D payment amount	0	0 percent
FUL amount between 0.01 and 20 percent above average Part D payment amount	57	11 percent
FUL amount between 20.01 and 50 percent above average Part D payment amount	51	9 percent
FUL amount between 50.01 and 100 percent above average Part D payment amount	47	9 percent
FUL amount more than 100 percent above average Part D payment amount	50	9 percent
Total Drugs	542	100 percent*

* Individual totals displayed in table do not add up to 100 percent because of rounding.

Source: OIG analysis of CMS FUL Data and PDE Data.

In the aggregate, AMP-based FUL amounts plus a dispensing fee would still exceed retail prices available through discount generic programs

Approximately half (279) of the drugs with an AMP-based FUL in the fourth quarter of 2007 were also included in at least one of the discount generic programs under review. Under the discount programs, each of these drugs had a retail price of \$4.00 for a 30-day supply (total cost, with no additional dispensing fees). The AMP-based FUL amounts for a 30-day supply of these same drugs averaged \$2.20, before any

F I N D I N G S

dispensing fees were applied.⁴³ However, given that only one State had a dispensing fee that was less than \$2.00 per prescription (New Hampshire was \$1.75), the average total Medicaid payment for these drugs, including the dispensing fee, would still exceed the retail prices under the discount generic programs.

As previously stated, if a Medicaid beneficiary obtained any of these 279 drugs from a pharmacy with a discount generic program, usual and customary charge provisions would generally apply. In other words, Medicaid should (and may) have reimbursed the pharmacy no more than a total of \$4.00 total for the drug, with no additional dispensing fee applied.

⁴³ As previously stated, State dispensing fees to retail pharmacies for generic drugs ranged from \$1.75 to \$7.25 per prescription, with fees in 30 States falling between \$3.50 and \$5.00.



R E C O M M E N D A T I O N

Based in part on OIG work that consistently found that the published prices used to set FUL amounts often greatly exceed prices available in the marketplace, the DRA included provisions to base FUL amounts on the AMP, rather than the prices published in national compendia. However, an injunction from a Federal judge, as well as provisions in the MIPPA, delayed the implementation of the AMP-based FULs. Therefore, CMS is still basing Medicaid FUL amounts on published prices until at least October 1, 2009.

The findings of this report demonstrate that the current method for setting the FUL amounts continues to result in substantially inflated Medicaid payments for many multiple-source drugs. The FUL amounts for individual drugs are frequently double (and often more than five times) the acquisition costs for pharmacies, the payment amounts under Part D, and even the prices charged by retail chain pharmacies. As a result, Medicaid could be overpaying by hundreds of millions of dollars per year for these drugs.

Our findings show that AMP-based FULs calculated under the DRA prescribed methodology significantly lessen the gap between the FUL amounts and the other prices we examined. In the aggregate, the DRA-based FULs seem to cover acquisition costs, and are very similar to overall Part D reimbursement. Considering that Medicaid's dispensing fees for multiple-source drugs tend to be higher than those paid by Part D plans, it is likely that pharmacies will continue to receive higher aggregate payments under Medicaid if and when the AMP-based FUL methodology takes effect.

Despite the aggregate numbers, we have concerns that for a number of individual drugs the AMP-based FUL amounts were substantially below average acquisition costs and Part D payment amounts. If this is the case, pharmacies may face difficulties in providing certain drugs to Medicaid beneficiaries. However, if and when CMS is permitted to publicly disclose AMP data, the resulting transparency should help ensure that the AMP-based FUL amounts are more accurate reflections of actual market prices. Furthermore, as CMS stated in a response to a previous OIG report, pharmacies will seek out the lowest-cost versions of the FUL drugs, meaning that looking at how "average" costs compare may not always reflect market realities. To that end, our analysis showed that 38 of the 50 drugs we reviewed were available from at least one source at a price below the AMP-based FUL amount.

R E C O M M E N D A T I O N

Notwithstanding these concerns, the inflated payments resulting from the pre-DRA methodology that we observed in this review once again illustrate the flaws in the current FUL calculation. We also understand that without a legislative change and the lifting of the injunction, CMS's options are limited at this time. However, it is critical that Medicaid set payment rates that are fair and appropriate to both the government and providers. Therefore, we recommend that:

CMS should continue to work with Congress to identify strategies that would lower inflated Medicaid payments for multiple-source drugs.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation. CMS also stated that our findings support the agency's belief that AMP-based FULs more accurately reflect acquisition costs and prices used in other programs. However, the agency expressed concerns with certain aspects of our methodology.

Specifically, CMS stated that actual pharmacy acquisition costs are likely to be lower than the estimates used in our report because two of the four responding distributors failed to provide data on price concessions. CMS believes that if all distributors had reported these price concessions, we would have found that more drugs had been obtainable at the AMP-based FUL amounts. CMS also noted that our findings understate Medicaid payment rates because we did not include dispensing fees that are paid when Medicaid prescriptions are filled.

Despite these issues, CMS recognized that for certain multiple-source drugs, acquisition costs may exceed the AMP-based FULs. However, the agency noted that FULs are required to be met only in the aggregate and that States have the authority to pay more than the FUL amount for certain drugs as long as total payments remain below the aggregate limit. In addition, CMS also stated that publicly disclosing AMP data will bring transparency to prices and assist pharmacies in purchasing drugs at less than the FUL amounts.

OIG acknowledged in the "Limitations" section on page 14 that two distributors did not provide data on price concessions, and therefore pharmacies' bottom-line costs for some drugs may be lower than the estimates used in the report. We agree that had these two distributors

R E C O M M E N D A T I O N

included information on price concessions, our estimate of the number of drugs available at prices below the AMP-based FUL amounts may have increased. However, based on our data, this limitation does not fundamentally change the underlying issue surrounding the availability of individual drugs. As Table 7 on page 23 shows, the AMP-based FUL amount was less than the average acquisition cost for 26 of the selected drugs; in 19 of these cases, the difference between the two amounts was greater than 20 percent. In other words, for many of these drugs, the AMP-based FUL amounts would likely have still been below average acquisition costs even if all distributors had reported price concessions.

In addition, except for one circumstance involving prices charged under discount retail programs, OIG did not consider dispensing fees in its pricing comparison. Medicaid FUL amounts are meant to reimburse pharmacies for the acquisition costs of the drugs themselves, while dispensing fees are separate payments that cover the additional costs of dispensing drugs. Because this study did not focus on these additional costs, it would not have been appropriate to include dispensing fees in most pieces of our analysis.

Finally, we agree that because FULs apply only in the aggregate, States have the flexibility to raise payment amounts for individual drugs (and lower payment amounts for others) if and when FUL amounts appear to be too low. However, in practice, it may prove challenging for States to try to determine the adequacy of individual FUL amounts for hundreds of drugs and make appropriate adjustments. Therefore, it is important to balance the goal of lower aggregate payment levels with the need to ensure that FUL amounts cover acquisition costs for as many drugs as possible.

For the full text of CMS's comments, see Appendix B.

Fifty Federal Upper Limit Drugs With Highest Total Medicaid Expenditures in 2007

Drug	Strength	Form
ACETAMINOPHEN/CODEINE	300 MG-30 MG	TAB
ACETAMINOPHEN/HYDROCODONE BITARTRATE	500 MG-10 MG	TAB
ACETAMINOPHEN/HYDROCODONE BITARTRATE	500 MG-5 MG	TAB
ACETAMINOPHEN/HYDROCODONE BITARTRATE	500 MG-7.5 MG	TAB
ALBUTEROL SULFATE	0.083%	SOL
ALPRAZOLAM	0.5 MG	TAB
ALPRAZOLAM	1 MG	TAB
AMOXICILLIN	500 MG	CAP
AMOXICILLIN	250 MG/5 ML	PDR
AMOXICILLIN/CLAVULANATE POTASSIUM	400 MG/5 ML-57 MG/5 ML	PDR
BACLOFEN	10 MG	TAB
BETAMETHASONE/CLOTRIMAZOLE	0.05%-1%	CRE
CEFPROZIL	250 MG/5 ML	PDR
CEPHALEXIN	500 MG	CAP
CLONAZEPAM	0.5 MG	TAB
CLONAZEPAM	1 MG	TAB
CLONIDINE HCL	0.1 MG	TAB
CYCLOBENZAPRINE HCL	10 MG	TAB
FLUOXETINE HCL	20 MG	CAP
FLUOXETINE HCL	40 MG	CAP
FOLIC ACID	1 MG	TAB
GABAPENTIN	300 MG	CAP
GABAPENTIN	400 MG	CAP
GABAPENTIN	600 MG	TAB
GABAPENTIN	800 MG	TAB
GLYBURIDE/METFORMIN HCL	5 MG-500 MG	TAB
HYDROXYZINE HCL	25 MG	TAB
IBUPROFEN	800 MG	TAB
LISINOPRIL	20 MG	TAB
LORAZEPAM	0.5 MG	TAB
LORAZEPAM	1 MG	TAB
LORAZEPAM	2 MG	TAB
METFORMIN	1000 MG	TAB
METFORMIN	500 MG	TAB
MUPIROCIN	2%	OIN
OMEPRAZOLE	20 MG	ECC
OXYCODONE HCL	20 MG	TER
OXYCODONE HCL	40 MG	TER
OXYCODONE HCL	80 MG	TER
OXYCODONE/ACETAMINOPHEN	325 MG-5 MG	TAB
OXYCODONE/ACETAMINOPHEN	650 MG-10 MG	TAB

Table Continued on Next Page

A P P E N D I X ~ A

Fifty Federal Upper Limit Drugs With Highest Total Medicaid Expenditures in 2007 (continued)

PAROXETINE	20 MG	TAB
PAROXETINE	40 MG	TAB
POTASSIUM CHLORIDE	20 MEQ	TER
PROPOXYPHENE NAPSYLATE & ACETAMINOPHEN	650 MG-100 MG	TAB
RANITIDINE HCL	150 MG	TAB
RIBAVIRIN	200 MG	CAP
SULFAMETHOXAZOLE/TRIMETHOPRIM	800 MG-160 MG	TAB
TRAMADOL HCL	50 MG	TAB
ZONISAMIDE	100 MG	CAP

Source: Office of Inspector General Analysis of Medicaid Utilization Data.

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

RECEIVED
2009 JUL 10 PM 2:25
OFFICE OF INSPECTOR GENERAL

JUL 9 2009

DATE:

TO: Daniel R. Levinson
Inspector General

FROM: Charlene Frizzera /S/
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "A Comparison of Medicaid Federal Upper Limit Amounts to Acquisition Costs, Medicare Payment Amounts, and Retail Prices" (OEI-03-08-00490)

Thank you for the opportunity to review and comment on the subject draft report. In this draft report, the OIG--(1) Determines how the current pre-Deficit Reduction Act of 2005 (DRA, P.L. 109-171) Federal upper limit (FUL) amounts compare to pharmacy acquisition costs, Medicare Part D payment amounts, and retail prices under discount generic programs; (2) Estimates the financial impact on the Medicaid program of continuing to calculate FUL amounts using the current method; and (3) Determines how FUL amounts based on average manufacturer prices (AMPs) calculated under the method required by the DRA compare to the pricing points under review.

The DRA required FUL amounts for multiple source drugs to be based on 250 percent of the lowest reported AMP in a FUL group. However, a preliminary injunction issued by the U.S. District Court for the District of Columbia and a moratorium in the Medicare Improvements for Patients and Providers Act of 2008 (P.L. 110-275) prevented the Centers for Medicare & Medicaid Services (CMS) from implementing the AMP-based FUL methodology until at least October 1, 2009. As a result, CMS is currently calculating FUL amounts under the pre-DRA methodology.

OIG Findings

Using fourth-quarter 2007 Medicaid drug utilization data, the OIG reviewed the top 50 drugs with the highest total Medicaid expenditures. The OIG found the following for the current, pre-DRA FULs.

- In the aggregate, the FUL amounts calculated under the current methodology were 4.32 times more than average pharmacy acquisition costs in the fourth quarter of 2007. For almost half of the drugs under review, the FUL amounts calculated under the current methodology were at least five times greater than the average pharmacy acquisition costs in the fourth quarter of 2007.

Page 2 – Daniel R. Levinson

- In the aggregate, the FUL amounts calculated under the current methodology were 2.91 times higher than average Part D payment amounts in the fourth quarter of 2007. This figure does not take into account that both Medicaid and Part D usually pay a dispensing fee in addition to the ingredient cost payment. Among individual drugs, in 51 out of 335 cases the FUL amounts calculated under the current methodology were at least five times higher.
- In the aggregate, the FUL amounts calculated under the current methodology were 1.97 times higher than prices available through retail discount generic programs in the fourth quarter of 2007.

The OIG concluded that despite the fact that States often pay less than the FUL amount for multiple source drugs, the current calculation using the pre-DRA methodology is still costing Medicaid hundreds of millions of dollars per year. The OIG notes that if Medicaid had paid for the 50 FUL drugs with the highest total expenditures under review based on the average pharmacy acquisition cost, the program would have reduced expenditures by \$105 million in a single quarter. Also, if Medicaid had paid for the 572 FUL drugs under review at the average Part D payment amount, the program would have reduced expenditures by \$138 million in a single quarter. Additionally, if Medicaid had paid all pharmacies for the 291 FUL drugs at the price available through retail discount generic programs, the Medicaid program would have reduced expenditures by \$87 million in a single quarter.

The OIG also analyzed the AMP-based FUL amounts and found that, in the aggregate, AMP-based FUL amounts were much closer to the pharmacy acquisition cost and the prices set by other programs. Specifically, the OIG found the following for the AMP-based FULs.

- In the aggregate, the fourth-quarter 2007 AMP-based FUL amounts were 50 percent higher than average pharmacy acquisition costs in the fourth quarter of 2007.
- In the aggregate, AMP-based FUL amounts were more than double the lowest pharmacy acquisition cost in the fourth quarter of 2007.
- In the aggregate, AMP-based FUL amounts were 2 percent below average Part D payment amounts for the fourth quarter of 2007. However, given that Medicaid tends to pay higher dispensing fees than Part D, State payments to pharmacies under the AMP-based FULs may actually exceed Part D payments in the aggregate once dispensing fees are considered.
- In the aggregate, the AMP-based FUL amounts, including a dispensing fee, would exceed the retail prices available under the discount generic programs.

Despite the aggregate numbers, the OIG has concerns that for a number of individual drugs the AMP-based FUL amounts were substantially below average acquisition costs and Part D payment amounts. The OIG contended that if this is the case, pharmacies may face difficulties in providing certain drugs to Medicaid beneficiaries. In response to CMS' previous comment that

Page 3 – Daniel R. Levinson

pharmacies will seek out the lowest cost versions of the FUL drugs, the OIG also examined the lowest acquisition costs reported by any wholesale distributor for any single version (i.e., national drug code) of a FUL drug. The OIG found that, in the aggregate, the AMP-based FUL amounts for 38 out of 50 drugs were higher than the lowest acquisition costs reported by wholesale distributors in the fourth quarter of 2007. In other words, pharmacies may have been able to purchase these versions from a particular distributor for less than the AMP-based FUL amount. The OIG also notes that if and when CMS is permitted to publicly disclose AMP data, the resulting transparency should help ensure that the AMP-based FUL amounts are a more accurate reflection of market prices.

CMS Response

In general, we concur with the findings in this report; however, we have concerns with certain aspects of the methodology used in the study. In reaching its conclusions, we believe the report overstates pharmacy acquisition costs by using data from distributors that failed to include price concessions, and it understates Medicaid payment rates by failing to include dispensing fees that are paid by Medicaid when prescriptions are filled.

As we have responded in prior OIG reports, we agree that the current pre-DRA methodology for setting the FUL amounts substantially inflates Medicaid payments for many multiple source drugs. We also appreciate the OIG's findings that the AMP-based FUL amounts more closely align with the actual acquisition costs of these drugs to pharmacies and believe that this confirms our response to the previous OIG report on AMP-based FULs.

In regard to the OIG's concern that for some individual drugs the AMP-based FULs may be below pharmacy acquisition costs and the Part D payment amounts, we recognize that the prices for certain multiple source drugs may exceed the FUL. However, we note that the FULs are calculated as an aggregate upper limit for the States and that the States have the flexibility to adjust payment amounts for any of these drugs. The fact that one drug might be above the limit does not mean that the State by paying more for that drug would not remain under the aggregate upper limit. States have broad authority under section 1902(a)(30) of the Social Security Act to establish payment rates under their State plan that are consistent with efficiency, economy, and quality of care and that are sufficient to enlist enough providers so that care under the plan is available at least to the extent that such services are available to the general population. Accordingly, States have discretion to adjust payment rates to ensure availability. We believe that FULs based on AMP data more accurately reflect pharmacy acquisition costs and prices used in other programs and that the report provides support for such AMP-based FULs. In addition, we also believe that publicly disclosing AMPs will bring transparency to these prices such that States can adjust payment rates and pharmacies will know which versions of the drugs can be purchased within the FUL amounts.

Finally, as noted previously, we have some concerns with the OIG's methodology. In obtaining acquisition cost data from the wholesalers, only two of the four responding wholesalers reported discounts and other price adjustments to their sales prices to pharmacies. Had all of the wholesalers reported such price concessions, we believe the pharmacy acquisition costs would

Page 4 – Daniel R. Levinson

have been lower than the estimates used in the report and that more drugs would have been obtainable at the AMP-based FUL amounts.

OIG Recommendation

The OIG recommends that CMS continue to work with Congress to identify strategies that would lower inflated Medicaid payments for multiple source drugs.

CMS Response

We concur. CMS will continue to work with Congress to find strategies to help lower inflated Medicaid payments for multiple source drugs.

We appreciate the work of the OIG in this report and hope that the findings of this report will help substantiate the need to align payment amounts to pharmacy acquisition costs.



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.

Eric M. Biersmith served as lead analyst for this study. Other central office staff who contributed include Eddie Baker, Jr., and Scott Manley.