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United States Government Accountability Office
Washington, DC 20548

December 22, 2006

The Honorable Joe Barton
Chairman
Committee on Energy and Commerce
House of Representatives

Subject: *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*

Dear Mr. Chairman:

Spending on outpatient prescription drugs in Medicaid—the joint federal-state program that finances medical services for certain low-income adults and children—has accounted for a substantial and growing share of Medicaid expenditures.[1] Medicaid's total spending on outpatient prescription drugs grew from $4.6 billion in fiscal year 1990 to $40 billion in fiscal year 2004—or from 7.0 to 14.2 percent of Medicaid's total expenditures for medical care. State Medicaid programs do not directly purchase prescription drugs; instead, they reimburse retail pharmacies for covered outpatient prescription drugs dispensed to Medicaid beneficiaries.[2] For some outpatient multiple-source prescription drugs, state Medicaid programs may only receive federal matching funds for reimbursements up to a maximum amount known as a federal upper limit (FUL).[3,4] Required by law as a cost-containment strategy, FULs are calculated as 150 percent of the lowest price for a drug, from among the

[1]Medicaid consists of 56 distinct programs created within broad federal guidelines and administered by state Medicaid agencies. The 56 Medicaid programs include one for each of the 50 states; the District of Columbia; Puerto Rico; and the U.S. territories of American Samoa, Guam, Northern Mariana Islands, and the Virgin Islands. Hereafter in this report, we use "state Medicaid programs" to refer to these 56 programs.

[2]Retail pharmacies are licensed nonwholesale pharmacies that are open to the public.

[3]FULs must be established for each multiple source drug for which there are three or more therapeutically equivalent drug products. 42 U.S.C. § 1396r-8(e)(4) (2000). Therapeutically equivalent drug products can be substituted with the full expectation that they will produce the same clinical effect as the prescribed drug.

[4]By regulation, FULs apply to multiple-source prescription drugs that the Food and Drug Administration considers to have at least three therapeutically equivalent versions and at least three manufacturers or suppliers. 42 C.F.R. § 447.301 and 447.332 (2005).

prices published nationally in three drug pricing compendia.[5] State Medicaid programs have the authority to determine their own reimbursements to retail pharmacies[6] for covered outpatient multiple-source prescription drugs, as long as those reimbursements do not exceed established FULs in the aggregate.

The Deficit Reduction Act of 2005 (DRA) included provisions that changed the methodology for calculating FULs.[7] Beginning January 1, 2007, a drug's FUL will be based on the average manufacturer price (AMP). AMP represents the average of prices paid to manufacturers by wholesalers for a drug distributed to the retail pharmacy class of trade, including retail pharmacies, and is typically less than any of a drug's published prices in the three pricing compendia. Each therapeutically equivalent version of a multiple-source drug has an AMP, and beginning January 1, 2007, a drug's FUL will be calculated as 250 percent of the lowest AMP from among a drug's therapeutically equivalent versions. The Congressional Budget Office estimated that when implemented, AMP-based FULs could reduce total Medicaid spending for prescription drugs by $3.6 billion from 2007 to 2010 and by about $11.8 billion from 2007 to 2015.[8]

Though representing a potential cost saving measure for Medicaid, the change in FUL calculation methodology—using AMP instead of the lowest published price—has raised concerns among retail pharmacies serving Medicaid beneficiaries. Drug manufacturers are required to report AMP data on their drugs to CMS. Because these data are not publicly available, retail pharmacies cannot determine what the relationship will be between AMP-based FULs and the prices the pharmacies pay to acquire these drugs.[9]

Because of your interest in the potential effects of the AMP-based FULs on retail pharmacies, you requested information on how AMP-based FULs will compare with retail pharmacy acquisition costs. We estimated what the AMP-based FULs would have been if they had applied in 2006 and compared them with average retail pharmacy acquisition costs from 2006 for frequently used and high expenditure multiple-source outpatient prescription drugs in Medicaid.

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[5]The Centers for Medicare & Medicaid Services (CMS), the agency that oversees Medicaid, identifies which drugs are subject to FULs. The Deficit Reduction Act of 2005 also included additional provisions relating to Medicaid reimbursement of outpatient prescription drugs.

[6]Many state Medicaid programs require retail pharmacies to dispense the lower cost therapeutically equivalent version of a drug to Medicaid beneficiaries when one is available. Under these mandatory generic substitution policies, the higher cost version of the drug remains available to beneficiaries if the prescribing physician receives prior authorization. In cases when retail pharmacies are authorized to dispense the higher cost version of the drug, the FUL does not apply.

[7]Pub. L. No. 109-171, § 6001, 120 Stat. 4, 54-59 (2006) (to be codified at 42 U.S.C. § 1396r-8).

[8]Congressional Budget Office Cost Estimate. S. 1932, Deficit Reduction Act of 2005. January 27, 2006.

[9]The price a retail pharmacy pays to acquire a drug from a manufacturer or wholesaler is known as a pharmacy's drug acquisition cost.

To estimate the AMP-based FULs and compare them with average retail pharmacy acquisition costs, we used first quarter 2006 Medicaid utilization data[10] to select a sample of multiple-source outpatient prescription drugs subject to Medicaid FULs. To develop our sample, we identified the 50 drugs that were the most frequently used—that is, represented 53 percent of the outpatient prescription drugs subject to FULs and dispensed to Medicaid beneficiaries in the first quarter of 2006—and the 50 drugs that were the highest expenditure—that is, accounted for 56 percent of Medicaid spending on outpatient prescription drugs subject to FULs in the first quarter of 2006,[11] with some drugs overlapping the two categories. Our resulting sample contained 77 multiple-source outpatient prescription drugs, which comprised 27 frequently used prescription drugs in Medicaid, 27 high expenditure prescription drugs in Medicaid, and 23 prescription drugs that overlapped both categories.

We obtained AMP data from the Centers for Medicare & Medicaid Services (CMS), which requires manufacturers to report AMP data within 30 days of the end of every calendar quarter. We obtained the average retail pharmacy acquisition cost data for the first quarter of 2006 from IMS Health, which obtains these data on sales transactions from approximately 100 manufacturers and over 300 distribution centers, including drug wholesalers and chain warehouses. These manufacturers and distribution centers are responsible for over 85 percent of total market dollar volume. IMS Health projects these data to represent national average acquisition costs for each drug in our sample in the first quarter of 2006.[12] The average pharmacy acquisition cost data that we obtained from IMS Health may be greater than actual acquisition costs because these data do not account for rebates that pharmacies may receive from wholesalers or manufacturers.[13]

For each of the 77 drugs in our sample, we estimated what the AMP-based FULs would have been had they applied in 2006. Using AMP data from the first quarter of 2006, we followed DRA provisions and selected the lowest AMP for each group of therapeutically equivalent versions and multiplied those AMPs by 250 percent. We did not exclude any outlier AMP data in order to be consistent with how CMS officials told us they will be implementing DRA provisions beginning January 1, 2007. We

[10]Medicaid utilization data reported to CMS include information on the total number of units and dollar amount for which state Medicaid programs reimbursed retail pharmacies for covered drugs dispensed to Medicaid beneficiaries. As of July 2006, when we selected our sample, utilization data from Iowa, Minnesota, New Jersey, and Rhode Island were not included because these states had not reported their Medicaid utilization data for the first quarter of 2006.

[11]In ranking drugs by their share of Medicaid expenditures for multiple-source outpatient prescription drugs in the first quarter of 2006, we excluded any dispensing fees paid to pharmacies as a part of state reimbursement formulas. Each state pays pharmacies, for each prescription dispensed, a professional dispensing fee intended to cover the pharmacy's labor and overhead costs, such as pharmacists' salaries, drug packaging, rent, and utilities.

[12]For any given drug, the acquisition costs of individual pharmacies may be higher or lower than the national average.

[13]These rebates may vary as retail pharmacies negotiate their rebates based on various factors, including the type of drug, manufacturer, and volume of purchases. In addition, they can negotiate rebates on a manufacturer's entire line of products rather than on a per-drug basis.

compared these estimated AMP-based FULs with average retail pharmacy acquisition cost data from the first quarter of 2006 for the 77 drugs in our entire sample and for each of the three categories of drugs our sample comprises—the frequently used drugs, the high expenditure drugs, and the drugs that overlapped both categories.[14] In order to assess the extent to which AMP-based FULs are likely to vary over time, we also examined the variation in lowest AMPs for the drugs in our sample from the third quarter of 2005 through the third quarter of 2006. We determined that the data used were sufficiently reliable for our purposes. For more detail on our scope and methodology, see enclosure I. The list of 77 drugs we reviewed is included in enclosure II. We performed our work from July 2006 through November 2006 in accordance with generally accepted government auditing standards.

Results in Brief

The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs in our sample. For our entire sample of 77 multiple-source outpatient prescription drugs, we found that these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. The extent to which the AMP-based FULs were lower than average retail pharmacy acquisition costs differed for high expenditure drugs compared with the frequently used drugs and the drugs that overlapped both categories. In particular, the estimated AMP-based FULs were, on average, 65 percent lower than average retail pharmacy acquisition costs for the 27 high expenditure drugs in our sample and 15 percent lower, on average, for the 27 frequently used drugs in our sample. For the 23 drugs that overlapped both categories of drugs, the estimated AMP-based FULs were, on average, 28 percent lower than the average retail pharmacy acquisition costs. In addition, we also found that the lowest AMPs for the 77 drugs in our sample varied notably from quarter to quarter. Despite this variation, when we estimated what the AMP-based FULs would have been using several quarters of historical AMP data, these estimated FULs were also, on average, lower than average retail pharmacy acquisition costs from the first quarter of 2006.

Though the difference between AMP-based FULs and retail pharmacy acquisition costs was in some cases sizable, the extent of this difference may change because of several factors, including the quarter-to-quarter variation in AMPs used to set FULs as well as the presence of rebates that retail pharmacies may obtain from drug manufacturers and wholesalers. To the extent that the utilization of multiple-source outpatient prescription drugs by retail pharmacies remains similar in 2007 and later to the utilization patterns captured in our sample of drugs for the first quarter of 2006, the gap between estimated first quarter 2006 AMP-based FULs and pharmacy acquisition costs could persist, once the AMP-based FULs are implemented in 2007. However, to the extent that the cost-containment measures of the AMP-based FULs influence pharmacies to acquire lower cost therapeutically equivalent versions of drugs or negotiate lower prices from manufacturers and wholesalers, the gap between AMP-based FULs and acquisition costs could be narrowed or offset.

[14]In our comparison of the AMP-based FULs and retail pharmacy acquisition costs, we did not consider dispensing fees.

In reviewing a draft of this report, CMS disagreed with our finding that the AMP-based FULs were lower than the average retail pharmacy acquisition costs for most of the 77 drugs in our sample. In particular, CMS had significant concerns with our estimates of both pharmacy acquisition costs and AMP-based FULs and stated that our findings had not accounted for changes in these two variables that are likely to take place after DRA provisions are implemented in January 2007. In our view, we used the most complete, accurate data sources available at the time of our analysis for our purposes—to estimate both retail pharmacy acquisition costs and AMP-based FULs, had the latter applied in the first quarter of 2006. Furthermore, in our draft report we identified the limitations of the data sources used in our estimates and acknowledged that the difference between retail pharmacy acquisition costs and AMP-based FULs could change following implementation of DRA provisions in 2007. Only after AMP-based FULs are implemented in 2007 will there be an opportunity to determine the extent to which these FULs facilitate both cost-effective Medicaid drug expenditures and adequate reimbursement for retail pharmacies.

Background

Medicaid is a joint federal-state entitlement program that finances medical services for certain low-income adults and children.[15] While federal guidelines require that all state Medicaid programs offer certain basic benefits, each state Medicaid program determines the extent to which it will cover optional benefits. Outpatient prescription drug coverage is an optional benefit that all state Medicaid programs have elected to include in their Medicaid benefit packages. State Medicaid programs do not directly purchase drugs; instead they reimburse retail pharmacies for covered outpatient prescription drugs dispensed to Medicaid beneficiaries. For some outpatient multiple-source prescription drugs, state Medicaid programs may only receive federal matching funds for reimbursements up to a maximum amount known as a FUL.

Medicaid Federal Upper Limits

FULs were first established in 1987 as a cost-containment strategy in an effort to limit the amount that Medicaid could reimburse retail pharmacies for certain multiple-source outpatient prescription drugs.[16] FULs have been established for multiple-source drugs that have at least three manufacturers or suppliers and CMS publishes a list of drugs that have FULs in the State Medicaid Manual.[17] FULs are expressed on a

[15]Within guidelines established by federal statutes, regulations, and policies, each state (1) establishes its own eligibility standards; (2) determines the type, amount, duration, and scope of services; (3) sets the rate of payment for services; and (4) administers its own program.

[16]52 *Fed. Reg.* 28,648 (July 31, 1987). Legislation was enacted in 1990 making the application of FULs a statutory requirement. (Pub. L. No. 101-508, sec. 4401(a)(3), § 1927(f)(2), 104 Stat. 1388, 1388-143 (to be codified, as amended by DRA § 6001(a)(1)–(2), 120 Stat. 54-55, at 42 U.S.C. § 1396r-8(e)(4)).

[17]In addition, FULs are only established when multiple-source drugs are listed as "A" rated-drug products—that is, that the Food and Drug Administration (FDA) considers to be therapeutically equivalent to other pharmaceutically equivalent products—in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*. This list is commonly known as the Orange Book and identifies drug products approved on the basis of safety and effectiveness by FDA.

per-unit basis—for example, per tablet. As of first quarter 2006, the list included more than 500 multiple-source drugs.[18]

CMS determines the FUL for a multiple-source outpatient prescription drug by grouping a drug's therapeutically equivalent versions together and setting a FUL for each group. Each of a drug's therapeutically equivalent versions has several published prices associated with it, including the average wholesale price (AWP),[19] wholesale acquisition cost (WAC),[20] and direct price (DP).[21] All of these prices are published in each of the three national drug pricing compendia—First DataBank, Medi-Span, and Red Book—which use different methods for determining these published prices. The lowest published price for a FUL group—that is, a drug—may be any one of these three prices, and this can vary depending on the FUL group. Until provisions in DRA take effect January 1, 2007, CMS sets a FUL by identifying a drug's therapeutic equivalent with the lowest price—either AWP, WAC, or DP—in any of the three national drug pricing compendia, and multiplying that price by 150 percent.

A state's total reimbursements for Medicaid prescription drugs subject to FULs must not exceed, in the aggregate, the payment levels established by the FULs over a year. States may exceed the FUL for an individual prescription drug as long as their aggregate expenditures for all prescription drugs subject to FULs do not exceed the amounts that are calculated using the rate established by the FUL.

State Medicaid programs consider several methods for reimbursing pharmacies for multiple-source prescription drugs. In general, states base their Medicaid reimbursements to a retail pharmacy for a covered outpatient prescription drug on the lowest of the following: a state's best estimate of retail pharmacies' acquisition costs for the drug;[22] the usual and customary charge of the retail pharmacy that dispensed the drug;[23] the FUL for the drug, if applicable; or the state's maximum allowable cost (MAC) for the drug,[24] if applicable. When the FUL for a drug is not the

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[18]Transmittal No. 37, Federal Upper Limit Drug List, November 20, 2001. Federal Upper Limit (FUL) Changes to Transmittal No. 37, June 23, 2006.

[19]AWP is the average of the list prices that the manufacturer suggests wholesalers charge pharmacies.

[20]WAC is the manufacturer's list price for wholesalers or other direct purchasers before any rebates, discounts, allowances, or other price concessions.

[21]DP as published by First DataBank represents the manufacturer's published catalog or list price for a drug product to nonwholesalers. DP does not represent actual transaction prices and does not include prompt pay or other discounts, rebates, or reductions.

[22]States may establish their own methodologies for estimating retail pharmacies' drug acquisition costs. Most states in the first quarter of 2006 chose to estimate these costs by taking a percentage discount from the AWP.

[23]The usual and customary charge for a drug is the full retail price that individuals without prescription drug coverage pay when purchasing drugs at a retail pharmacy.

[24]States that administer MACs publish lists of selected multiple-source drugs with the maximum price at which the state will reimburse for those medications. Pharmacies generally do not receive payments that are higher than the MAC price. The MAC lists differ from the FUL list, as states have more

lowest of these four amounts, Medicaid typically reimburses pharmacies at a rate lower than the FUL.

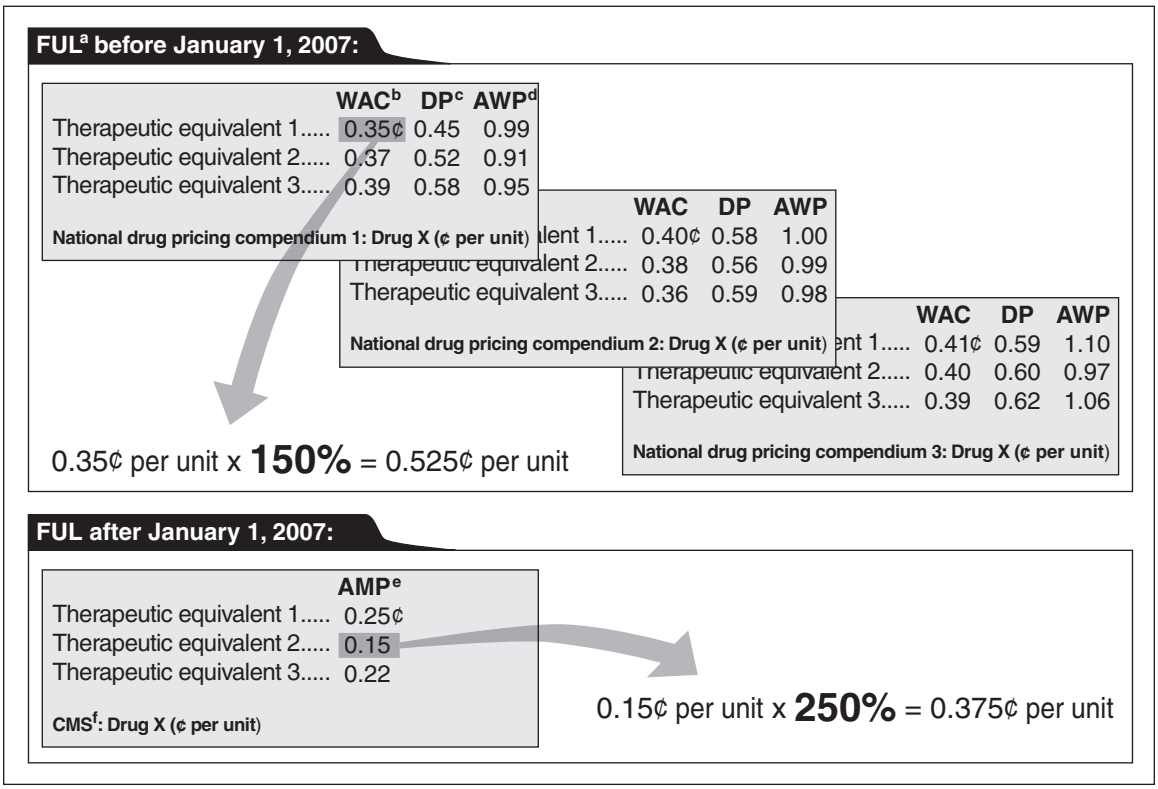
Deficit Reduction Act of 2005 and Medicaid FULs

DRA modified the methodology used to set FULs for certain multiple-source outpatient prescription drugs for Medicaid.[25] Rather than 150 percent of the lowest published price of the therapeutically equivalent versions, starting January 1, 2007, DRA required that CMS calculate FULs as 250 percent of the lowest AMP among a drug's therapeutically equivalent versions. AMP data are collected by CMS and are not publicly available. (Fig. 1 illustrates how Medicaid FULs are calculated before and after DRA provisions take effect January 1, 2007.)

discretion in determining what drugs to include on their MAC lists. Generally, state MAC lists include more drugs, and establish lower reimbursement prices, than the FUL list. As of first quarter 2006, 43 states administer MACs.

[25]DRA § 6001,120 Stat. 54-59.

Figure 1: Illustration of FUL Methodology Before and After January 1, 2007



Source: GAO.

Note: The drug pricing compendia in fig.1 are published by First DataBank, Medi-Span, and Red Book.

[a]FUL is the federal upper limit for reimbursement of certain Medicaid outpatient prescription drugs.

[b]WAC is the manufacturer's list price for wholesalers or other direct purchasers before any rebates, discounts, allowances, or other price concessions.

[c]DP as published by First DataBank represents the manufacturer's published catalog or list price for a drug product to nonwholesalers. DP does not represent actual transaction prices and does not include prompt pay or other discounts, rebates, or reductions.

[d]AWP is the average of the list prices that the manufacturer suggests wholesalers charge pharmacies.

[e]AMP represents the average of prices paid to manufacturers by wholesalers for a drug distributed to the retail pharmacy class of trade, including retail pharmacies.

[f]CMS is the agency that oversees Medicaid.

DRA included additional provisions relating to prescription drugs. One provision changed the criteria under which FULs must be established. Until January 1, 2007, FULs must be established for multiple-source drugs for which there are three or more therapeutically equivalent products.[26] Beginning on January 1, 2007, the DRA provides that FULs be established for multiple-source drugs for which there are at least two therapeutically equivalent products.[27] DRA also mandated several changes relating to

[26]42 U.S.C. § 1396r-8(e)(4) (2000).

[27]DRA § 6001(a)(1), 120 Stat. 54 (to be codified at 42 U.S.C. § 1396r-8(e)(4)).

the AMP. For example, DRA required that prompt payment discounts be excluded when manufacturers calculate AMP. DRA also required the Secretary of Health and Human Services to make manufacturers' reported AMP data available on a monthly basis to states, and to post those amounts on a Web site accessible to the public beginning July 2006.[28] These requirements were established in order to give states pricing information that was not previously available to consider in setting reimbursement amounts.

Estimated AMP-Based FULS Were Lower Than Average Pharmacy Acquisition Costs for Most Drugs in our Sample

For most of the 77 drugs in our sample, the AMP-based FULs we estimated using AMP data from the first quarter of 2006 were lower than average retail pharmacy acquisition costs for the same period. In particular, the percentage difference between the estimated AMP-based FULs and average retail pharmacy acquisition costs was more pronounced for high expenditure drugs than it was for frequently used drugs. Though lowest AMPs can vary notably from quarter to quarter, when we estimated what AMP-based FULs would have been using several quarters of AMP data we found that that these estimated FULs were also lower than average retail pharmacy acquisition costs for most of the drugs—and in particular the high expenditure drugs—in our sample. Furthermore, the difference between AMP-based FULs and retail pharmacy acquisition costs could change following the implementation of DRA provisions in January 2007, to the extent that retail pharmacies acquire lower cost therapeutically equivalent versions of drugs or negotiate lower prices from manufacturers and wholesalers.

Based on First Quarter 2006 Data, AMP-Based FULs Were Lower Than Average Acquisition Costs, with Difference Most Pronounced for High Expenditure Drugs

The AMP-based FULs we estimated using first quarter 2006 AMP data were lower than the average retail pharmacy acquisition costs for the same period for most—59 out of 77—of the drugs in our sample. The estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for our entire sample of drugs.[29] Further, for 43 of the 77 drugs, we found that the estimated AMP-based FULs fell below the lowest acquisition cost available to retail pharmacies. While the estimated AMP-based FULs were lower than average retail pharmacy acquisition costs for our entire sample of drugs, this difference was most pronounced for the 27 high expenditure drugs, compared with the 27 frequently used drugs and with the 23 drugs that were both high expenditure and frequently used in our sample.

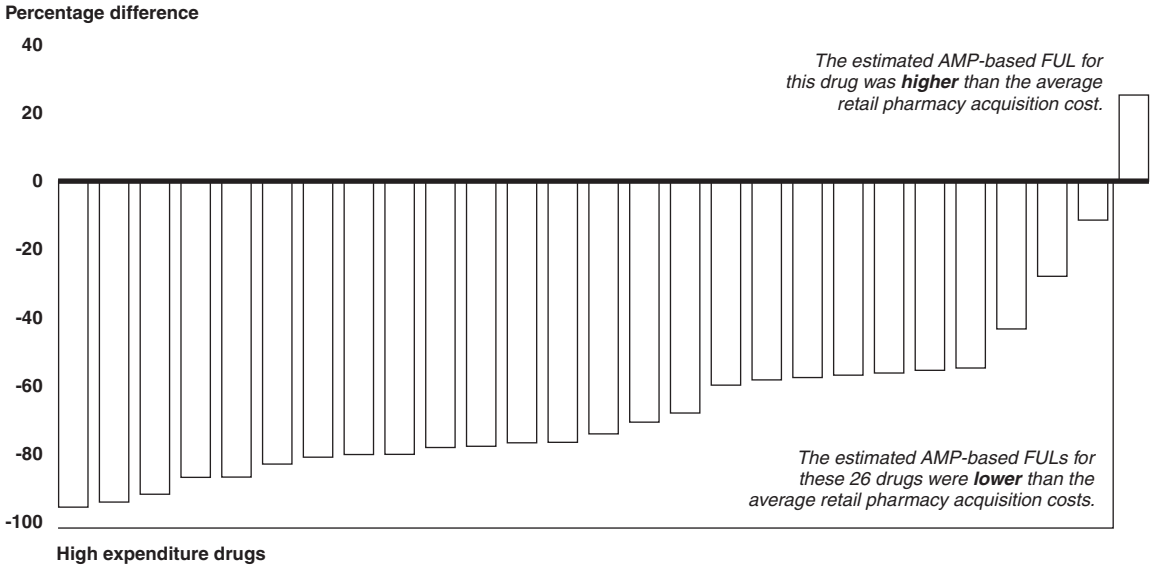
[28]While CMS released AMP data to states starting in July of 2006, the implementation of the provision requiring AMP data to be posted on a publicly available Web site has been delayed until January 1, 2007.

[29]Excluding statistical outliers from our analysis resulted in a less than 1 percent change in the average percent difference between average retail pharmacy acquisition costs and estimate AMP-based FULs.

High Expenditure Drugs

For 26 of the 27 high expenditure drugs in our sample, the AMP-based FULs we estimated using first quarter 2006 data were lower than the average retail pharmacy acquisition costs for this period (see fig. 2). The estimated FULs for these 27 drugs were, on average, 65 percent lower than average retail pharmacy acquisition costs.[30] We also found that for 21 of the 27 high expenditure drugs, the estimated AMP-based FULs fell below the lowest acquisition cost available to retail pharmacies.

Figure 2: Comparison of Estimated AMP-Based FULs and Average Retail Pharmacy Acquisition Costs for 27 High Expenditure Outpatient Drugs in Medicaid, First Quarter 2006



Source: GAO analysis of AMP data from CMS and average retail pharmacy acquisition cost data from IMS Health.

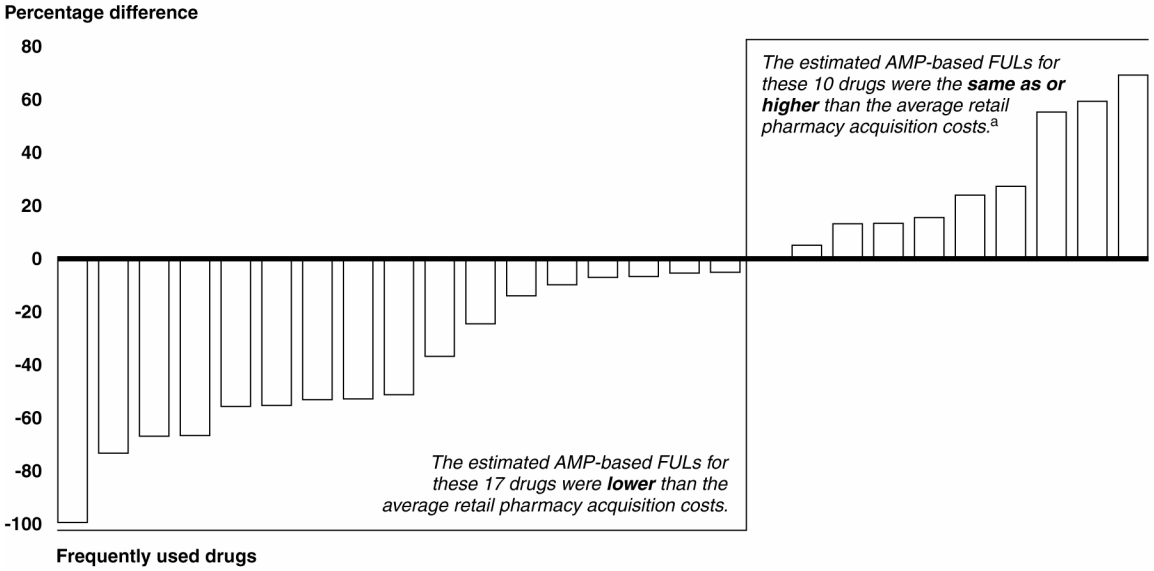
Frequently Used Drugs

For 17 of the 27 frequently used drugs in our sample, the AMP-based FULs we estimated using first quarter 2006 data were lower than the average retail pharmacy acquisition costs for this period (see fig. 3). For these 27 frequently used drugs, the estimated AMP-based FULs were, on average, 15 percent lower than average retail pharmacy acquisition costs.[31] We also found that for 11 of the 27 frequently used drugs, the estimated AMP-based FULs fell below the lowest acquisition cost available to retail pharmacies.

[30]In the first quarter of 2006 the average acquisition cost per unit for the 27 high expenditure drugs in our sample was $0.49.

[31]In contrast with the average acquisition cost per unit for the 27 high expenditure drugs in our sample—$0.49—the average acquisition cost per unit for the 27 frequently used drugs was $0.05 in the first quarter of 2006.

Figure 3: Comparison of Estimated AMP-Based FULs and Average Retail Pharmacy Acquisition Costs for 27 Frequently Used Outpatient Drugs in Medicaid, First Quarter 2006



Source: GAO analysis of AMP data from CMS and average retail pharmacy acquisition cost data from IMS Health.

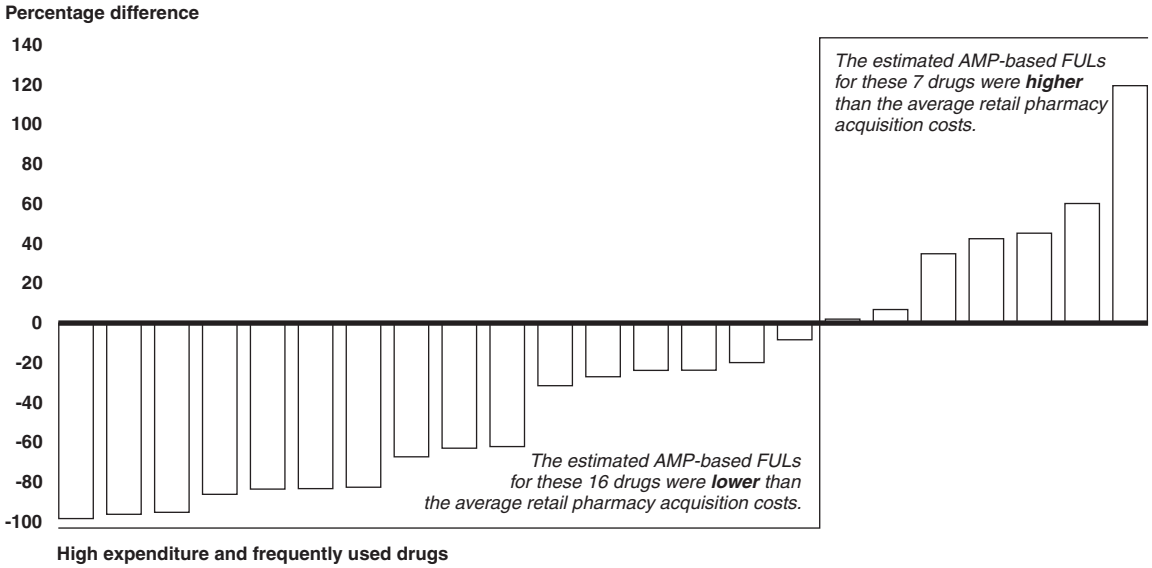
[a]One drug had an estimated AMP-based FUL the same as the average retail pharmacy acquisition cost.

High Expenditure and Frequently Used Drugs

For 16 of the 23 drugs that were both high expenditure as well as frequently used, the AMP-based FULs we estimated using first quarter 2006 AMP data were lower than the average retail pharmacy acquisition costs for this period (see fig. 4). Further, the estimated AMP-based FULs for the 23 drugs were, on average, 28 percent lower than average retail pharmacy acquisition costs.[32] We also found that for 11 of these 23 drugs the estimated AMP-based FULs fell below the lowest acquisition costs available to retail pharmacies.

[32]For the 23 high expenditure and frequently used drugs, the average acquisition cost per unit was $0.08.

Figure 4: Comparison of AMP-Based FULs and Average Retail Pharmacy Acquisition Costs for 23 Outpatient Drugs That Were Both High Expenditure and Frequently Used in Medicaid, First Quarter 2006



Source: GAO analysis of AMP data from CMS and average retail pharmacy acquisition cost data from IMS Health.

Though Lowest AMPs Can Vary Over Time, AMP-Based FULs Estimated for Several Quarters Were Also Lower Than Acquisition Costs

Our comparison of estimated AMP-based FULs and average retail pharmacy acquisition costs involves AMP data that can vary notably from quarter to quarter. In particular, we found variation in the lowest AMPs—which will set AMP-based FULs, beginning January 1, 2007—for the 77 drugs in our sample. For example, from the first of quarter 2006 through the second quarter of 2006,

- 36 of the 77 drugs had a median increase of 33 percent in their lowest AMPs;
- 11 of the 77 drugs had no change in their lowest AMPs; and
- 30 of the 77 drugs had a median decrease of 33 percent in their lowest AMPs.

Similarly, the lowest AMPs for the 77 drugs in our sample varied from quarter to quarter over the period covering the third quarter of 2005 through the third quarter of 2006. Despite this variation in lowest AMP values, when we estimated what AMP-based FULs would have been in each of several quarters—namely, the fourth quarter of 2005 through the second quarter of 2006—we found that the estimated FULs for each of these quarters were also lower, on average, than average retail pharmacy acquisition costs from the first quarter of 2006.[33] Even if we made the comparison using the quarter—from among the fourth quarter of 2005 through the second quarter of 2006—in which each drug's estimated AMP-based FUL was the highest, the

[33]This analysis assumes that first quarter 2006 acquisition costs are a valid proxy for acquisition costs in the fourth quarter of 2005 and the second quarter of 2006.

estimated AMP-based FULs for 49 of the 77 drugs remained lower than first quarter 2006 average retail pharmacy acquisition costs. Across our entire sample of 77 prescription drugs, the estimated AMP-based FULs were 12 percent lower, on average, than the average retail pharmacy acquisition costs from the first quarter of 2006. This analysis also showed differences across the three groups of drugs in our sample:

- For the high expenditure drugs, AMP-based FULs for 24 out of 27 drugs remained lower than average retail pharmacy acquisition costs. Across this group of drugs, the estimated AMP-based FULs were 41 percent lower, on average, than the average retail pharmacy acquisition costs from the first quarter of 2006.

- For frequently used drugs, AMP-based FULs for 10 out of 27 drugs remained lower than average retail pharmacy acquisition costs. Across this group of drugs, the estimated AMP-based FULs were 11 percent higher, on average, than the average retail pharmacy acquisition costs from the first quarter of 2006.

- For the high expenditure and frequently used drugs, AMP-based FULs for 15 out of 27 drugs remained lower than average retail pharmacy acquisition costs. Across this group of drugs, the estimated AMP-based FULs were 4 percent lower, on average, than the average retail pharmacy acquisition costs from the first quarter of 2006.

Difference between AMP-Based FULs and Retail Pharmacy Acquisition Costs Could Change Following Implementation of DRA Provisions in 2007

Though the difference between AMP-based FULs and retail pharmacy acquisition costs in the first quarter of 2006 was in some cases sizable—on average 65 percent for the high expenditure drugs in our sample—it is important to recognize that the extent of this difference may change, because of several factors. These factors include the quarter-to-quarter variation in the AMPs used to set FULs, the DRA-required change in the definition of AMP that excludes prompt payment discounts from the calculation of AMPs, which may increase AMPs, and the presence of rebates that retail pharmacies may obtain from drug manufacturers and wholesalers that may lower retail pharmacy acquisition costs. In addition, because FULs apply to state Medicaid program aggregate expenditures for relevant outpatient multiple-source drugs in a year, states may reimburse for some drugs in excess of the FULs as long as these higher reimbursements are offset by others that are below the FULs.

Furthermore, the difference we found between AMP-based FULs and retail pharmacy acquisition costs also reflects the particular multiple-source outpatient prescription drugs pharmacies purchased and dispensed to Medicaid beneficiaries in the first quarter of 2006. To the extent that in 2007 and in future years this utilization remains similar to the utilization captured in our sample of drugs for the first quarter of 2006, the gap we found could persist. However, to the extent that the cost-containment measures of the AMP-based FULs influence retail pharmacies to acquire lower cost therapeutically equivalent versions of drugs or negotiate lower prices from manufacturers and wholesalers, the gap between AMP-based FULs and acquisition costs could be narrowed or offset. Only after AMP-based FULs are implemented in

2007 will there be an opportunity to determine the extent to which these FULs are facilitating both cost-effective Medicaid drug expenditures and adequate reimbursements for retail pharmacies.

Agency and Other External Comments

CMS reviewed a draft of this report and provided written comments, which are reproduced in enclosure III. CMS disagreed with our finding that the AMP-based FULs were lower than the average retail pharmacy acquisition costs for most of the 77 drugs in our sample. In particular, CMS had significant concerns with our estimates of both pharmacy acquisition costs and AMP-based FULs and stated that our findings had not accounted for changes in these two variables that are likely to take place after DRA provisions are implemented in January 2007. In our view, we used the most complete, accurate data sources available at the time of our analysis for our purposes—to estimate both retail pharmacy acquisition costs and AMP-based FULs, had the latter applied in the first quarter of 2006. Furthermore, in our draft report we identified the limitations of the data sources used in our estimates and acknowledged that the difference between retail pharmacy acquisition costs and AMP-based FULs could change following implementation of DRA provisions in 2007.

In its written comments, CMS raised issues regarding our estimates of retail pharmacy acquisition costs, our estimates of AMP-based FULs, and our discussion of the impact of DRA provisions:

Our Estimates of Retail Pharmacy Acquisition Costs

CMS stated that our draft report did not provide source documents or evidence of how IMS Health arrived at the acquisition costs used in our comparison. Our draft report explained that IMS Health collects acquisition cost data from actual sales transactions from manufacturers and distribution centers, which represent over 85 percent of total market dollar volume, and projects these data to represent national average acquisition costs. We could not provide CMS with the acquisition cost data used in our analysis because, while they are commercially available, they are proprietary. Specifically, our data use agreement with IMS Health prohibits us from releasing its data to third parties, such as CMS.

CMS also questioned the validity of our estimation of retail pharmacy acquisition costs because we did not account for the rebates retail pharmacies may receive from wholesalers and manufacturers. In our draft report we stated that the IMS Health data did not account for such rebates, and we identified this as a limitation of our analysis. However, as CMS officials acknowledged to us, there are no known data sources of pharmacy acquisition costs of multiple-source outpatient prescription drugs that account for rebates. Identifying rebates is difficult because retail pharmacies negotiate their rebates based on various factors and can negotiate rebates on a manufacturer's entire line of products rather than on a per-drug basis. We have amended our report to clarify these issues.

Our Estimates of AMP-Based FULs

CMS stated that in estimating the AMP-based FULs for our analysis we did not exclude outlier AMP data. According to CMS, excluding outlier AMP data could have "significantly" raised our estimates of AMP-based FULs for many multiple-source outpatient prescription drugs. As we stated in our draft report, we did not exclude outlier AMP data from our analysis because, during the course of our work, CMS officials indicated that they would not exclude any outlier AMP data when they begin calculating AMP-based FULs in January 2007. To be consistent with the methodology CMS indicated the agency will use when implementing DRA provisions, we did not exclude outlier data from our estimates of AMP-based FULs. However, in their comments, CMS indicated that they intend to address outlier AMP data, as appropriate, in calculating the AMP-based FULs.

During the course of our work we identified outliers in the AMP data underlying the FULs for several drugs in our analysis. However, excluding these outliers did not significantly reduce the gap we found between the estimated AMP-based FULs and retail pharmacy acquisition costs. We have amended our report to include this information. We agree with CMS's revised approach to publish clear criteria for (1) identifying and excluding outliers from the AMP data that underlie each FUL group and (2) identifying which therapeutically equivalent versions of each drug are nationally available and should thereby be considered when setting the FUL.[34]

Potential Impact of DRA on Retail Pharmacy Acquisition Costs and AMP-Based FULs

CMS stated that our analysis did not account for several ways in which DRA may affect retail pharmacy acquisition costs and the AMP-based FULs. CMS suggested that our estimation of retail pharmacy acquisition costs will likely not reflect such costs after the implementation of DRA provisions in January 2007. CMS expects that the AMP-based FULs implemented as a result of DRA will drive retail pharmacies to fill more Medicaid prescriptions with lower cost versions of multiple-source outpatient prescription drugs—thereby reducing these pharmacies' acquisition costs. In CMS's view, our study erroneously assumed that pharmacies' utilization of multiple-source outpatient prescription drugs—and therefore pharmacy acquisition costs—will remain unchanged after the implementation of DRA. While we estimated average pharmacy acquisition costs for the multiple-source outpatient prescription drugs in our sample using utilization and cost data from the first quarter of 2006, we also acknowledged in our draft report that retail pharmacies could change their utilization of multiple-source outpatient prescription drugs in 2007 and later to lower their acquisition costs. Specifically, our draft report stated that "to the extent that the cost-containment measures of the AMP-

[34]In a media release dated December 15, 2006, CMS indicated that it will publish in the *Federal Register* a proposed rule to implement provisions of the Deficit Reduction Act of 2005 that highlights proposed changes in the payment for certain drugs in the Medicaid program. See http://www.cms.hhs.gov/apps/media/fact_sheet.asp (December 15, 2006).

based FULs influence pharmacies to acquire lower cost therapeutically equivalent versions of drugs or negotiate lower prices from manufacturers and wholesalers, the gap between AMP-based FULs and acquisition costs could be narrowed or offset."

CMS also pointed out that our study did not include an analysis of how retail pharmacies could mitigate the effects of AMP-based FULs by filling more Medicaid prescriptions with lower cost versions of multiple-source outpatient prescription drugs. However, as part of our analysis, we compared estimated AMP-based FULs to the lowest available acquisition cost for each of the multiple-source outpatient prescription drugs in our sample. As we reported in our draft, for most the drugs in our sample—43 of 77—the estimated AMP-based FUL fell below the lowest acquisition cost available to retail pharmacies.

CMS had concerns that in estimating the AMP-based FULs we used AMP data that included customary prompt payment discounts, even though DRA requires their exclusion from AMP beginning in 2007. According to CMS, prompt payment discounts decrease AMPs, and so using AMP data that include such discounts will decrease AMP-based FULs. In our view, the impact of excluding prompt payment discounts from the AMP data we used to estimate AMP-based FULs is unclear. In our previous work, we have found that prompt payment discounts are, on average, 2 percent of the sales transactions to which they apply.[35] However, we have also reported that manufacturers vary in the purchasers to whom they offer prompt payment discounts and whether they include these discounts in their calculations of AMP. Therefore, attempting to account for prompt payment discounts for all of the multiple-source outpatient prescription drugs in our analysis would have, in some cases, overstated the impact of these discounts on our estimates of AMP-based FULs. We agree with CMS that the changes in the definition of AMP as required by DRA will likely increase AMP-based FULs. However, our previous work suggests that excluding prompt payment discounts from the calculation of AMP-based FULs would not have offset the gap we reported between retail pharmacy acquisition costs and estimated AMP-based FULs. In our report, we have clarified the issue of prompt payment discounts and its impact on our analysis.

In addition to their concerns related to the estimates used in our draft report, CMS noted that our analysis did not address existing state cost containment efforts, such as MAC programs, to reduce Medicaid reimbursements for outpatient prescriptions drugs. While the relationship between AMP-based FULs and state Medicaid cost containment efforts is a valid comparison, the issue was beyond the scope of our report, which compared estimated AMP-based FULs to retail pharmacy acquisition costs.

[35]See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102 (Washington, D.C.: Feb. 4, 2005).

Finally, we agree with CMS that changing the basis of the FUL from the AWP to the AMP was a step in the right direction towards achieving savings for the federal government on Medicaid expenditures for multiple-source outpatient prescription drugs. However, these savings should be achieved while ensuring that reimbursements to retail pharmacies are adequate to provide Medicaid beneficiaries access to multiple-source outpatient prescription drugs. As we stated in our draft report, only after AMP-based FULs are implemented in 2007 will there be an opportunity to determine the extent to which these FULs facilitate both cost effective Medicaid drug expenditures and adequate reimbursement for retail pharmacies.

CMS also provided technical comments that we incorporated as appropriate.

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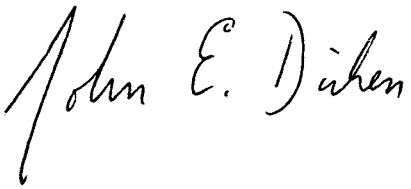
As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its date. We will then send copies of this report to the Administrator of CMS and other interested parties. The report will also be available at no charge on GAO's Web site at http://www.gao.gov. If you or your staff have any questions about this report, please contact me at (202) 512-7119 or dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs can be found on the last page of this report. GAO staff who made major contributions to this report are listed in enclosure IV.

Sincerely yours,



John E. Dicken
Director, Health Care

Enclosures—4

Scope and Methodology

To examine the relationship between the Medicaid federal upper limits (FUL) estimated using first quarter 2006 average manufacturer price (AMP) data and the average retail pharmacy acquisition cost for frequently used and high expenditure drugs in Medicaid, we used first quarter 2006 Medicaid utilization data from the Centers for Medicare & Medicaid Services (CMS)[36] to select the 50 most frequently used and the 50 highest expenditure multiple-source outpatient prescription drugs in Medicaid subject to FULs.[37] Combined, these two lists comprised a sample of 77 unique drugs representing 53 percent of Medicaid prescriptions and 56 percent of Medicaid expenditures for drugs subject to the FUL in the first quarter of 2006.[38] We obtained the list of drugs subject to the FUL from CMS and, because the AMP-based FULs were not available during the course of our work, estimated what the AMP-based FULs would have been using AMP data from the first quarter of 2006 for each of the 77 drugs.

Our analyses are limited to multiple-source outpatient prescription drugs that were subject to FULs for the first quarter of 2006 and do not include those drugs that may be added to the FUL list beginning January 1, 2007, per the expanded multiple-source definition in the Deficit Reduction Act of 2005 (DRA). Additionally, we compared corresponding AMP data with retail pharmacy acquisition cost data for each drug in our sample by National Drug Codes (NDC).[39]

To estimate FULs under the AMP-based methodology, we first extracted AMP data for the first quarter of 2006 for each of the 77 drugs in our sample from CMS's Medicaid Drug Rebate Initiative (MDRI) system. CMS requires manufacturers to report AMP data within 30 days of the end of every calendar quarter. We then selected the lowest AMP for the first quarter of 2006 for each group of therapeutically equivalent drugs and multiplied it by 250 percent. These AMP data do not account for the impact of the DRA-required change in the definition of AMP which excludes

[36]Medicaid utilization data reported to CMS include information on the total number of units and dollar amounts reimbursed for each drug. As of August 2006 when we selected our sample, Iowa, Minnesota, New Jersey, and Rhode Island had not reported their Medicaid utilization data for the first quarter of 2006.

[37]For drugs subject to the FUL, Medicaid covered 32.9 million prescriptions that were dispensed to Medicaid beneficiaries at retail pharmacies in the first quarter of 2006.

[38]Drugs with the same name but different strengths, forms (such as capsules or tablets), or package sizes were counted separately as unique drugs.

[39]NDCs are the universal product identifiers for drugs for human use. The Food and Drug Administration assigns the first segment of the NDC, which identifies the firm that manufacturers, repackages, or distributes a drug; the second segment identifies a specific strength, dosage form, and formulation for a particular firm; and the third segment identifies package size. A single drug can have multiple NDCs associated with it. For example, a drug made by one manufacturer, in one form or strength, but in three package sizes would have three NDCs. Three-segment NDCs are denoted by 11 digits while two-segment NDCs are denoted by 9 digits, and do not account for package size.

prompt payment discounts.[40] In addition, in estimating the AMP-based FULs, we did not exclude any outlier AMP data in order to be consistent with how CMS officials told us they will be implementing DRA provisions beginning January 1, 2007. Nonetheless, during the course of our work, we examined the AMP data underlying each FUL group for the presence of statistical outliers.

To determine retail pharmacies' acquisition costs for the 77 drugs, we purchased national average retail pharmacy acquisition cost data from IMS Health for the first quarter of 2006. IMS Health obtains these data on sales transactions from approximately 100 manufacturers and over 300 distribution centers, including drug wholesalers and chain warehouses. These manufacturers and distribution centers are responsible for over 85 percent of total market dollar volume. IMS Health projects these data to represent national average acquisition costs for each drug in our sample in the first quarter of 2006.[41] The average pharmacy acquisition cost data that we obtained from IMS Health may be greater than actual average acquisition costs because these data do not account for rebates that pharmacies may receive from wholesalers or manufacturers.[42] We calculated an average acquisition cost for each drug by weighting the acquisition cost for each therapeutically equivalent drug by its Medicaid expenditure for first quarter 2006.[43]

To compare the estimated AMP-based FULs to the average retail pharmacy acquisition costs for each of the 77 drug groups in our analysis, we calculated the percentage difference between the AMP-based FUL and (1) the average of acquisition costs for all therapeutically equivalent drugs within a group and (2) the average acquisition cost for the lowest cost therapeutically equivalent drug within a group. We also calculated the percentage difference of the AMP-based FUL to the average acquisition cost and minimum acquisition cost separately for the 27 high expenditure drugs, 27 frequently used drugs, and 23 drugs that were considered both high expenditure and frequently used.

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[40]In our previous work we found that prompt payment discounts are, on average, 2 percent of the sales transactions to which they apply. However, we have also reported that manufacturers vary in the purchasers to whom they offer prompt payment discounts and whether they include these discounts in their calculations of AMP. Therefore, attempting to account for prompt payment discounts for all of the multiple-source outpatient prescription drugs in our analysis would have, in some cases, overstated the impact of these discounts on our estimates of AMP-based FULs. See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102 (Washington, D.C.: Feb. 4, 2005).

[41]For any given drug, the acquisition costs of individual pharmacies may be higher or lower than the national average.

[42]These rebates may vary as retail pharmacies negotiate their rebates based on various factors, including the type of drug, manufacturer, and volume of purchases. In addition, they can negotiate rebates on a manufacturer's entire line of products rather than on a per-drug basis.

[43]We calculated a weighted average acquisition cost to account for Medicaid prescription drug utilization patterns.

We also assessed the extent to which AMP-based FULs are likely to vary over time by examining the variation of the lowest AMPs that would be used to set the estimated FULs for each of the 77 drugs in our sample from the third quarter of 2005 through the third quarter of 2006. Additionally, we compared the highest estimated AMP-based FUL from the fourth quarter of 2005 through the second quarter of 2006 to the average retail pharmacy acquisition cost for the first quarter of 2006 for each of the 77 drugs. We also performed this comparison separately for the 27 high expenditure drugs, 27 frequently used drugs, and 23 drugs that were considered both high expenditure and frequently used.

To assess the reliability of the AMP data, we reviewed relevant documentation regarding the construction and reporting of data extracted from CMS's MDRI system. To assess the reliability of the IMS Health average retail pharmacy acquisition cost data, we reviewed relevant documentation regarding the construction and reporting of the data supplied. We determined that the data used were sufficiently reliable for our purposes.

We performed our work from July 2006 through November 2006 in accordance with generally accepted government auditing standards.

Percentage of Medicaid Prescriptions and Expenditures for 77 Medicaid Outpatient Prescription Drugs GAO Reviewed, First Quarter 2006

Drug name and strength	Dosage form	Percentage of Medicaid prescriptions	Ranking by Medicaid prescriptions	Percentage of Medicaid expenditures	Ranking by Medicaid expenditures
Acetaminophen Codeine Phosphate 300-30mg	Tablet	1.2	14	0.5	49
Acetaminophen Hydrocodone Bitartrate 500-5mg	Tablet	3.2	2	0.5	47
Acetaminophen Hydrocodone Bitartrate 500-7.5mg	Tablet	0.9	27	N/A	N/A
Acetaminophen Hydrocodone Bitartrate 500-10mg	Tablet	0.6	43	1.1	17
Acetaminophen Hydrocodone Bitartrate 750-7.5mg	Tablet	0.6	45	N/A	N/A
Acetaminophen Oxycodone HCl 325-5mg	Tablet	1.2	17	N/A	N/A
Acetaminophen Propoxyphene Napsylate 650-100mg	Tablet	1.1	19	0.6	42
Albuterol 0.9mg/inh	Aerosol	3.7	1	1.8	9
Albuterol Sulfate 0.083mg/ml	Solution	1.8	4	2.0	6
Alprazolam 0.25mg	Tablet	0.6	38	N/A	N/A
Alprazolam 0.5mg	Tablet	0.9	26	N/A	N/A
Alprazolam 1mg	Tablet	0.8	29	N/A	N/A
Amoxicillin 125/5mg/ml	Suspension	1.9	3	0.5	50
Amoxicillin 500mg	Capsule	1.6	5	N/A	N/A
Amoxicillin Clavulanic Acid 400/5mg/ml-57/5mg/ml	Suspension	N/A	N/A	1.9	7
Atenolol 25mg	Tablet	0.6	40	N/A	N/A

Drug name and strength	Dosage form	Percentage of Medicaid prescriptions	Ranking by Medicaid prescriptions	Percentage of Medicaid expenditures	Ranking by Medicaid expenditures
Atenolol 50mg	Tablet	0.8	33	N/A	N/A
Baclofen 10mg	Tablet	N/A	N/A	0.7	30
Baclofen 20mg	Tablet	N/A	N/A	0.6	41
Betamethasone Dipropionate Clotrimazole 0.05-1%	Cream	N/A	N/A	0.8	23
Carbamazepine 200mg	Tablet	N/A	N/A	0.6	45
Carisoprodol 350mg	Tablet	0.6	44	0.8	24
Cephalexin 500mg	Capsule	1.0	22	0.7	36
Ciprofloxacin HCl 500mg	Tablet	0.5	49	N/A	N/A
Clonazepam 0.5mg	Tablet	1.3	11	0.7	29
Clonazepam 1mg	Tablet	1.1	18	0.9	21
Clonidine HCl 0.1mg	Tablet	1.0	24	N/A	N/A
Cyclobenzaprine HCl 10mg	Tablet	1.0	23	0.7	34
Diazepam 5mg	Tablet	0.6	42	N/A	N/A
Fluoxetine HCl 20mg	Capsule	1.0	21	0.7	33
Fluoxetine HCl 40mg	Capsule	N/A	N/A	1.2	16
Folic Acid 1mg	Tablet	1.2	15	N/A	N/A
Furosemide 20mg	Tablet	0.9	28	N/A	N/A
Furosemide 40mg	Tablet	1.4	7	N/A	N/A
Gabapentin 100mg	Capsule	N/A	N/A	0.7	32
Gabapentin 300mg	Capsule	0.7	36	5.1	1
Gabapentin 400mg	Capsule	N/A	N/A	1.3	12
Gabapentin 600mg	Tablet	N/A	N/A	4.2	2
Gabapentin 800mg	Tablet	N/A	N/A	2.0	5
Glimepiride 4mg	Tablet	N/A	N/A	0.5	46

Drug name and strength	Dosage form	Percentage of Medicaid prescriptions	Ranking by Medicaid prescriptions	Percentage of Medicaid expenditures	Ranking by Medicaid expenditures
Glyburide 5mg	Tablet	N/A	N/A	0.8	26
Glyburide Metformin HCl 5mg	Tablet	N/A	N/A	1.1	18
Hydrochlorothiazide 25mg	Tablet	1.5	6	N/A	N/A
Hydroxyzine HCl 25mg	Tablet	N/A	N/A	0.8	27
Ibuprofen 400mg	Tablet	0.6	46	N/A	N/A
Ibuprofen 600mg	Tablet	1.1	20	N/A	N/A
Ibuprofen 800mg	Tablet	1.4	8	N/A	N/A
Levothyroxine Sodium 0.05mg	Tablet	0.6	47	N/A	N/A
Lisinopril 10mg	Tablet	0.8	32	0.6	44
Lisinopril 20mg	Tablet	0.7	37	0.6	39
Lisinopril 40mg	Tablet	N/A	N/A	0.6	40
Lorazepam 0.5mg	Tablet	1.3	10	0.9	20
Lorazepam 1mg	Tablet	1.2	16	1.3	13
Lorazepam 2mg	Tablet	N/A	N/A	0.6	43
Lovastatin 40mg	Tablet	N/A	N/A	0.7	35
Metformin HCl 500mg	Tablet	1.2	12	1.8	8
Metformin HCl 1000mg	Tablet	0.6	41	1.0	19
Metoprolol Tartrate 50mg	Tablet	0.8	30	N/A	N/A
Metronidazole 500mg	Tablet	0.5	50	N/A	N/A
Mirtazapine 15mg	Tablet	N/A	N/A	0.8	28
Mirtazapine 30mg	Tablet	N/A	N/A	0.7	37
Mupirocin 2%	Ointment	N/A	N/A	1.2	15
Naproxen 500mg	Tablet	0.8	31	N/A	N/A
Omeprazole 20mg	Capsule	N/A	N/A	1.4	10

Drug name and strength	Dosage form	Percentage of Medicaid prescriptions	Ranking by Medicaid prescriptions	Percentage of Medicaid expenditures	Ranking by Medicaid expenditures
Paroxetine HCl 10mg	Tablet	N/A	N/A	0.6	38
Paroxetine HCl 20mg	Tablet	N/A	N/A	2.3	3
Paroxetine HCl 30mg	Tablet	N/A	N/A	0.8	22
Paroxetine HCl 40mg	Tablet	N/A	N/A	1.2	14
Penicillin V Potassium 500mg	Tablet	0.5	48	N/A	N/A
Potassium Chloride 20mEq	Tablet	0.8	34	0.8	25
Ranitidine HCl 150mg	Tablet	1.3	9	0.5	48
Ribavirin 200mg	Capsule	N/A	N/A	2.1	4
Sulfamethoxazole Trimethoprim 800-160mg	Tablet	1.0	25	N/A	N/A
Tizanidine HCl 4mg	Tablet	N/A	N/A	0.7	31
Tramadol HCl 50mg	Tablet	1.2	13	1.3	11
Trazodone HCl 50mg	Tablet	0.8	35	N/A	N/A
Trazodone HCl 100mg	Tablet	0.6	39	N/A	N/A

Source: GAO analysis of CMS Medicaid state drug utilization data.

Note: Our sample contained 77 multiple-source outpatient prescription drugs in Medicaid for the first quarter of 2006, which comprised 27 frequently used prescription drugs, 27 high expenditure prescription drugs, and 23 prescription drugs that overlapped both categories. N/A appears in the table for drugs that were not in the overlap category.

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CMS Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

DEC - 6 2006

Administrator
Washington, DC 20201

TO: John Dicken
Director, Health Care
Government Accountability Office

FROM: Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Government Accountability Office (GAO) Draft Report: "Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs" (GAO-07-239R)

Thank you for the opportunity for the Centers for Medicare & Medicaid Services (CMS) to comment on the proposed report on Federal Upper Limit (FUL) reimbursement and retail pharmacy acquisition cost. This report examines the potential effects on retail pharmacies of the provision of the Deficit Reduction Act of 2005 (DRA) that requires CMS to set the FUL at 250 percent of the lowest average manufacturer price (AMP) (computed without regard to customary prompt pay extended to wholesalers) in a FUL group.

Section 1927(e)(4) of the Social Security Act requires the Secretary to establish a Federal upper reimbursement limit for certain multiple source drugs. By regulation, this limit has been set as 150 percent of the least costly therapeutically equivalent drug as listed in published compendia of cost information for drugs for sale nationally.

It has been routinely reported that, over time, the FUL was increasingly less effective in assuring that the Medicaid program paid appropriately for multiple source drugs. This fact had been documented by studies of the Inspector General of the Department of Health and Human Service (HHS), by the bi-partisan Medicaid Commission, and in testimony before the House Energy and Commerce Committee. Over time, the reported prices used to set the FUL in published compendia have become less reliable as estimates of the true acquisition cost of drugs. As long as States must rely on prices that are not based on verifiable data, reimbursement is inflated, increasing the cost to Medicaid. In mandating the use of AMP, Congress required that the reimbursement system be based on reliable data and not on self-reported manufacturer's or distributor's data that is subject to bias. The DRA changes are intend to make transparent accurate pricing data to assure that the Federal government and state Medicaid programs are paying appropriately for multiple source drugs.

Enclosure III

This GAO study responds to concerns of the retail pharmacy industry that establishing a FUL reimbursement based on 250 percent of AMP will be insufficient to cover retail pharmacists' costs of purchasing drugs. If this were true, the actual AMP of a drug, as reported by manufacturers, multiplied by 2.5 would be less than a pharmacy's purchase price, meaning that the handling costs and profits in the distribution chain far exceed the actual cost of the drug product.

This GAO study purports to document that the AMP-based FULs are lower than average retail pharmacy acquisition cost for the 77 FUL drug groups reviewed. We find GAO's conclusion premature and unsupported by the report. This study cannot be thoroughly analyzed or replicated because the GAO will not release the data on which it is based. It admittedly uses incomplete and misleading information, as well as nondisclosed pricing data. We believe a more thorough analysis of pharmacy acquisition costs is necessary, based on verifiable and complete data, before any report is released.

GAO Findings

Using first quarter 2006 Medicaid data, 50 drugs that were identified as the most frequently used drugs, and 50 drugs that accounted for the highest Medicaid expenditures were selected for the study. With some drugs overlapping the two categories, the resulting sample contained 77 multiple source drugs groups.

The GAO determined that for 59 of the 77 multiple source drug groups analyzed in the study, the AMP-based FUL was lower than average retail pharmacy acquisition cost. On average, GAO estimated that the AMP-based FUL was 36 percent lower than average retail pharmacy acquisition cost. For high expenditure drugs, GAO estimated that the AMP-based FUL was 65 percent lower, and it was 15 percent lower for the frequently used drugs. For the drugs that overlapped both categories, the estimated AMP-based FUL was 28 percent lower than average retail pharmacy acquisition cost.

CMS Response

Based on the methodological flaws discussed below, we do not concur with the GAO findings that the AMP-based FUL would be lower than average retail pharmacy acquisition cost. The GAO study fails to credibly document this finding and we believe the release of the report would mislead the public.

The CMS has significant concerns with the validity of the estimate GAO used to approximate pharmacist acquisition costs. The CMS is unable to validate the findings of the GAO related to average retail pharmacy acquisition cost. The report does not provide source documents or evidence of how IMS Health arrived at the acquisition cost used in the comparison study other than to state that data on sales transactions were collected. Specifically, IMS cost and utilization data by national drug code (NDC) was not provided to CMS. This brings into question the overall validity of this self-reported data. Further, the GAO states in their report that "the average pharmacy acquisition cost data that we obtained from IMS Health may be greater than actual average acquisition cost,

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because these data do not account for rebates that pharmacies may receive from wholesalers or manufacturers." Thus, even were the GAO to supply this data, we cannot determine the accuracy of the ingredient cost actually incurred by the pharmacy. Therefore, CMS has no confidence that the estimates used in this analysis adequately measure pharmacy acquisition costs.

The CMS has concerns that GAO failed to account for the differences in the definitions of AMP. The AMP data from first quarter 2006 used in this study is not a true reflection of the AMP data which will be submitted starting in January 2007. 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 AMP. Since prompt pay discounts decrease AMPs, their exclusion would have the effect of increasing AMPs, and subsequently increasing the FULs. The absence of this factor in the analysis further calls into question the validity of GAO's findings.

The GAO also did not report on the effect that excluding outlier data would have on AMP-based FULs. The regulations, modified by the DRA, provide that FULs be set on drugs that are nationally available. We expect to address the elimination of outlier AMP data from use in calculating the FUL, as may be appropriate, before applying these new AMP-based FULs. Excluding outlier AMPs may significantly raise the FULs of many FUL groups and would further invalidate the GAO's findings.

The CMS has concerns that GAO's findings do not take into account the impact of existing state cost-containment mechanisms such as Maximum Allowable Cost (MAC) programs. While this report notes that States have MAC programs that further reduce the reimbursement used by States for multiple source drugs below the FULs, it fails to evaluate this effect on the GAO's overall comparison between acquisition costs and FULs. While we continue to disagree with the GAO's use of the average retail pharmacy acquisition cost, the report should at least compare the pharmacy acquisition cost to current State MACs instead of just the FUL.

The GAO study assumed that prescribing and filling practices will remain the same following the DRA change. In light of the DRA , we believe that assuming the same utilization of drugs within each of the 77 drug groups is incorrect. The GAO study provided no analysis of how States and pharmacies can mitigate the effect of the lower FULs by filling prescriptions with low cost generic equivalent drugs. We expect, with the implementation of the DRA provisions, that utilization will be driven to lower-priced generic versions of drugs, which will decrease costs in the overall. In addition, the GAO report fails to acknowledge that the FUL is not applied to brand name drugs when a physician certifies that these are medically necessary.

Prior Office of Inspector General reports have outlined the need for reform in Medicaid pharmacy reimbursement. The FUL amounts prior to DRA often exceeded pharmacy acquisition costs, and thus, increased cost to the States and the Federal Government. Using 250 percent of the lowest reported AMP rather than the current methodology of

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150 percent of the lowest price published in national compendia will reduce Medicaid expenditures for multiple source drugs and thus, result in billions of dollars of savings to States and the Federal Government.

Attachment

GAO Contact and Staff Acknowledgments

GAO Contact

John E. Dicken, (202) 512-7119 or dickenj@gao.gov

Acknowledgments

In addition to the contact named above, Martha Kelly, Assistant Director; Rashmi Agarwal; Shamonda Braithwaite; Krister Friday; Yung Park; and Daniel Ries made key contributions to this report.

(290556)

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