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United States Government Accountability Office
Washington, DC 20548

November 30, 2009

The Honorable Charles E. Grassley
Ranking Member
Committee on Finance
United States Senate

Subject: *Medicaid Outpatient Prescription Drugs: Second Quarter 2008 Federal Upper Limits for Reimbursement Compared with Average Retail Pharmacy Acquisition Costs*

Dear Senator Grassley:

Medicaid—the joint federal-state program[1] that finances medical services for certain low-income adults and children—spent $15.0 billion on outpatient prescription drugs in fiscal year 2007.[2] Instead of directly purchasing drugs, state Medicaid programs reimburse retail pharmacies for dispensing them to Medicaid beneficiaries.[3] The federal government provides matching funds to states to help cover the costs of their Medicaid programs, and states must pay the remaining costs to qualify for these federal funds.

For certain outpatient 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).[4] Designed to control drug spending, FULs are currently calculated as 150 percent of a drug's lowest published price in three national drug pricing compendia.[5] State Medicaid programs can determine reimbursements to retail pharmacies for each drug,[6] but the federal

[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; and the U.S. territories of American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the Virgin Islands. In this report, we use "states" and "state Medicaid programs" to refer to these 56 programs.

[2]Includes $22.3 billion in gross prescription drug expenditures which are offset by $7.3 billion in drug rebates paid by manufacturers to state Medicaid programs.

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

[4]The Centers for Medicare and Medicaid Services (CMS)—the agency that oversees Medicaid—identifies which drugs are subject to FULs.

[5]The drug pricing compendia are published by private companies including First DataBank, Medi-Span, and Red Book.

[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.

government will only provide matching funds to the extent that reimbursements for all drugs subject to FULs do not exceed established FULs in the aggregate.[7]

A 2005 report by the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) found that FULs were ineffective at controlling outpatient Medicaid prescription drug spending. The Deficit Reduction Act of 2005 (DRA) included provisions—the implementation of which has been delayed by judicial and legislative action—that would change the methodology for calculating FULs.[8] Under the DRA, FULs would be calculated as 250 percent of the average manufacturer price (AMP) for a drug's least costly therapeutically equivalent version.[9] In 2006, the Congressional Budget Office estimated that the implementation of AMP-based FULs would reduce total Medicaid spending for prescription drugs by $11.8 billion from 2007 through 2015.

However, retail pharmacies have raised concerns that AMP-based FULs would not be sufficient to cover their costs of acquiring drugs dispensed to Medicaid beneficiaries.[10] Two retail pharmacy industry groups, the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA), have claimed that AMP-based FULs would make some retail pharmacies unprofitable and thus limit certain Medicaid beneficiaries' access to retail pharmacies. A 2006 GAO report and a 2007 report by the HHS OIG both found that AMP-based FULs would have been lower than average pharmacy acquisition costs, on a drug-by-drug basis, for most drugs included in the respective samples.[11]

To implement the DRA provisions pertaining to prescription drugs in Medicaid, CMS published a final rule in July 2007.[12] This rule includes provisions regarding the calculation of AMP-based FULs that might also affect how they compare to pharmacy acquisition costs. For example, FULs apply only to certain outpatient prescription drugs—known as multiple-

[7]For the group of drugs subject to FULs, CMS applies FULs at the aggregate level rather than at the individual drug level when determining the level of federal payments for a state's Medicaid prescription drug expenditures. To calculate FULs at the aggregate level for a state, the FUL for each drug is multiplied by the total number of units of each drug that were reimbursed by a state Medicaid program and the total is summed across all drugs subject to FULs. Therefore, it might be possible for a state Medicaid program to reimburse pharmacies at an amount above the FULs for certain drugs if it also reimburses them at an amount below the FULs for other drugs.

[8]Pub. L. No. 109-171, § 6001(a)(2), 120 Stat. 4, 54-55 (2006) (codified at 42 U.S.C. § 1396r-8(e)(5)).

[9]AMP represents the average of prices paid to manufacturers in the United States by wholesalers for a drug distributed to the retail pharmacy class of trade, including independent pharmacies, chain pharmacies, and mail order pharmacies, and is typically less than any of a drug's published prices in the three pricing compendia. 42 U.S.C. § 1396r-8(k)(1)(A). Under the DRA, manufacturers are required to submit monthly AMPs no later than 30 days after the end of the prior month. See 42 U.S.C. § 1396r-8(b)(3)(A)(i); 42 C.F.R. §§ 447.504(a), (e); 447.510(d) (2008). The DRA also provided for CMS to disclose AMP data to the states and (through an accessible Web site) to the public. 42 U.S.C. § 1396r-8(b)(3)(D)(iv)-(v).

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

[11]See GAO, *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*, GAO-07-239R (Washington, D.C.: Dec. 22, 2006) and HHS OIG, *Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program*, OEI-03-06-00400 (Philadelphia, Pa.: June 2007).

[12]72 *Fed. Reg.* 39142 (July 17, 2007).

source drugs—and the rule changed the definition of multiple-source drugs.[13] Additionally, to minimize the effect of outliers, the final rule included a provision which would use the second-lowest AMP for a multiple-source drug to set the FUL if the lowest AMP is less than 40 percent of the second-lowest AMP.[14] The final rule requires drug manufacturers to report AMP data on a monthly basis, and drug manufacturers and state Medicaid programs were expected to begin complying with the provisions of the final rule by October 1, 2007.[15]

Although the AMP reporting requirements for pharmaceutical manufacturers have gone into effect, AMP-based FULs have not been implemented. In December 2007, as a result of litigation initiated by NACDS and NCPA, the U.S. District Court for the District of Columbia issued a preliminary injunction which prohibits CMS from implementing the final rule to the extent that it would affect Medicaid reimbursement rates for retail pharmacies and from disclosing AMP data reported by drug manufacturers, except under limited circumstances. As of October 1, 2009, that injunction remained in effect. Additionally, Congress passed legislation—the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)—that prohibited CMS from taking any action to implement the AMP-based FULs or publicly disclose AMP data before October 1, 2009.[16]

To assist congressional consideration of this matter in light of the concerns that have been expressed by retail pharmacies; changes in the calculation of AMP-based FULs;[17] and the October 1, 2009, expiration of the MIPPA provision delaying implementation of the AMP-based FUL, you requested that we reexamine the relationship between the AMP-based FULs that would be required under the DRA and pharmacies' average acquisition costs. This report examines the relationship between these AMP-based FULs and average retail pharmacy acquisition costs for selected drugs and provides additional information on how these FULs would affect retail pharmacies.

[13]A drug is considered a multiple-source drug when at least one other drug is therapeutically and pharmaceutically equivalent, as well as bioequivalent and is generally available to the public through retail pharmacies within a state. 42 U.S.C. § 1396r-8(k)(7)(A)(i); 42 C.F.R. § 447.502 (2008). Therapeutically equivalent drug products can be substituted with the full expectation that they will produce the same clinical effect as the prescribed drug. Under the 2007 final rule, a multiple-source drug that is available through two or more suppliers is subject to the FUL.

[14]42 C.F.R. § 447.514(c)(2)(2008). For example, if there are three therapeutically equivalent versions of a drug, with AMPs of $.01, $.04, and $.05, the version with an AMP of $.04 would be used to set the FUL, because $.01 is less than 40 percent of $.04. This provision applies only when there are at least three therapeutically equivalent versions of the drug available.

[15]42 C.F.R. § 447.510(d)(2008). Consistent with the DRA, the final rule also stated that FULs would be established for multiple-source drugs for which there were at least two therapeutically and pharmaceutically equivalent products. Previously, FULs were required only when there were at least three such products. 42 U.S.C. 1396r-8(e)(4); 42 C.F.R. § 447.514(a)(2008).

[16]Pub. L. No. 110-275, § 203, 122 Stat. 2494, 2592 (2008).

[17]Pending legislation would require changes to the calculation of AMP-based FULs. *See*, *e.g.*, H.R. 3962, 111th Cong. § 1741 (2009).

To compare AMP-based FULs with average retail pharmacy acquisition costs, we acquired from CMS a list of drugs that would have been subject to AMP-based FULs for the second quarter of 2008[18] but for the judicial and legislative action discussed above.[19] We then used Medicaid utilization data from the second quarter of 2008 to identify drugs with the highest Medicaid utilization and drugs with the highest Medicaid expenditures on a national level.[20] Our resulting sample contained 83 multiple-source outpatient prescription drugs: 32 drugs with the highest Medicaid utilization, 34 drugs with the highest Medicaid expenditures, and 17 drugs that appeared in both categories. Our sample of 83 drugs represented 64 percent of total Medicaid utilization and 52 percent of total Medicaid expenditures for drugs that would have been subject to AMP-based FULs in the second quarter of 2008. See enclosure I for a complete list of the 83 drugs in our sample and each drug's classification—high utilization, high expenditure, or both—in the second quarter of 2008.

For each of the 83 drugs in our sample, for April, May, and June of 2008, we obtained monthly AMP values for every therapeutically equivalent version as well as monthly AMP-based FUL data from CMS. We then used the monthly AMP-based FULs from April, May, and June 2008 to calculate the median AMP-based FULs for the second quarter of 2008.[21] We also obtained national average retail pharmacy acquisition cost data for the second quarter of 2008 for all therapeutically equivalent versions of the drugs in our sample from IMS Health, a contractor. On a monthly basis, IMS Health collects data on drugs purchased by retail pharmacies from about 100 drug manufacturers and about 500 distribution centers. These manufacturers and distribution centers provide data on the number of units sold, and a portion of them provide data on actual retail pharmacy acquisition costs. For those manufacturers and distribution centers that only provide data on the number of units sold, IMS Health estimates retail pharmacy acquisition costs based on the actual acquisition cost data it was able to obtain from others. Once IMS Health determines average retail pharmacy acquisition costs from data it collects, it projects these data to represent national average retail pharmacy acquisition costs using a model that is reviewed monthly.[22] In addition, IMS Health conducts detailed data reliability assessments, which include comparing monthly data from drug manufacturers and distribution centers to data from the prior month and the prior year in order to ensure consistency and comparing reported pricing data against published prices. The national average retail pharmacy acquisition cost data that we obtained from IMS Health

[18]The second quarter of 2008 was the most recent quarter for which most states had reported their utilization data to CMS at the time we began our analysis.

[19]Throughout this report, "AMP-based FULs" refer to what the FULs would have been if they had been calculated using 250 percent of the AMP, as specified in the DRA.

[20]Medicaid utilization data reported to CMS include information on the dollar amount and total number of units for which state Medicaid programs reimbursed retail pharmacies for covered drugs dispensed to Medicaid beneficiaries. As of July 2009, when we selected our sample, utilization data from Alabama, Arizona, Rhode Island, and Tennessee, and the U.S. territories of American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the Virgin Islands were not available. Therefore, our analysis is limited to 46 states and the District of Columbia.

[21]We calculated the median FUL for the second quarter of 2008 from the 3 months of FUL data provided by CMS in order to compare the quarterly FUL data to the quarterly average pharmacy acquisition cost data.

[22]For any given therapeutically equivalent version of a drug, the actual acquisition costs of individual retail pharmacies may be higher or lower than the national average we obtained from IMS Health.

do not account for rebates and discounts that pharmacies may receive from wholesalers or manufacturers, if they are not reflected in invoice prices.[23]

To examine the relationship between AMP-based FULs and average retail pharmacy acquisition costs by individual drug, we compared the quarterly median AMP-based FULs we calculated for the second quarter of 2008 with the average retail pharmacy acquisition costs, weighted by utilization across all therapeutically equivalent versions of each drug, from the same period for each of the 83 drugs in our sample. We also examined the relationship between AMP-based FULs and average pharmacy acquisition costs in the aggregate by comparing the AMP-based FULs with the average pharmacy acquisition costs for our entire sample of drugs weighted by utilization. Because our sample of 83 drugs does not include all drugs that would have been subject to AMP-based FULs in the second quarter of 2008, our aggregate results cannot be generalized beyond our sample. Because the utilization of each drug in our sample differs from state to state, we performed this analysis at both the national and state levels using state utilization data and national average pharmacy acquisition costs. Further, we compared the AMP-based FULs with the average pharmacy acquisition costs for each of the therapeutically equivalent versions of all 83 drugs in our sample. This analysis allowed us to estimate the extent to which pharmacies may be able to purchase therapeutically equivalent versions of each drug at costs below the AMP-based FUL. Specifically, we determined the percentage of Medicaid utilization represented by therapeutically equivalent versions with pharmacy acquisition costs that are above the AMP-based FULs, as well as the percentage of Medicaid utilization represented by therapeutically equivalent versions with acquisition costs that are below the AMP-based FULs. To assess the extent to which AMP-based FULs vary over time, we obtained AMP data from CMS for January 2008 through December 2008 and examined the variation in AMP-based FULs for the drugs in our sample across those months. Based on the results of this analysis, we interviewed CMS officials about the factors that led to the month-to-month variation in the FULs and how this variation may affect state Medicaid programs.

We discussed our data sources with knowledgeable officials from CMS and IMS Health. We also performed data reliability checks to test the internal consistency and reliability of the data, including manually and electronically checking the data for missing values and obvious errors, interviewing CMS officials about concerns we uncovered about AMP data, and reviewing steps that CMS uses to ensure that AMP data are complete and accurate. After taking these steps, we determined that the data were sufficiently reliable for our purposes. We conducted this performance audit from June 2009 through October 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[23]These discounts and rebates may vary, as retail pharmacies negotiate them based on various factors, including the type of drug, manufacturer, and volume of purchases. In addition, retail pharmacies can negotiate rebates on a manufacturer's entire line of products rather than per drug. We were unable to identify any data sources of acquisition costs for multiple-source outpatient prescription drugs that account for these reductions in the cost of drugs to retail pharmacies.

Results in Brief

If AMP-based FULs had been in place in the second quarter of 2008, they would have been lower than average retail pharmacy acquisition costs, in general, for most of the drugs in our sample and in the national aggregate.[24] The median AMP-based FULs for the second quarter of 2008 would have been lower than average retail pharmacy acquisition costs for 54 of the 83 drugs in our sample; 44 drugs had FULs that would have been at least 25 percent below acquisition costs. In the aggregate, the FULs would have been 17 percent lower than acquisition costs, though the difference varied significantly by state, from 57 percent lower to 49 percent higher. However, 64 drugs had at least one therapeutically equivalent version with acquisition costs below the FUL, indicating that pharmacies may be able to substitute lower-priced therapeutic equivalents to bring their costs below the FUL. AMP-based FULs also varied significantly throughout 2008 for 38 drugs, in some cases exceeding the average retail pharmacy acquisition cost one month and falling below it in another month. While partly due to monthly increases or decreases in AMPs, variation also occurred because manufacturers did not report AMP data each month for 11 percent of the therapeutically equivalent versions of the drugs in our sample. If a manufacturer reports the AMP for the lowest-priced therapeutically equivalent version of a drug one month but does not report it the next month, the FUL may change.

In its written comments on a draft of this report, CMS disagreed with our finding that if AMP-based FULs had been in place in the second quarter of 2008, they would have been lower than average retail pharmacy acquisition costs for most of the 83 drugs in our sample and in the national aggregate. See enclosure IV for CMS's comments. In particular, CMS expressed concerns about our data source used to estimate average retail pharmacy acquisition costs, including that it does not take into account discounts and rebates that drug manufacturers may provide to retail pharmacies. CMS also expressed concerns about our methodology and inconsistencies between our finding and the findings of an HHS-OIG report, which the OIG shared with us because it has not been publicly issued as of November 2009. However, as we indicate in this report, data on discounts and rebates pharmacies receive are not readily available. We used the most complete, accurate, and verifiable data sources available at the time of our analysis to estimate average retail pharmacy acquisition costs. We believe that these data are sufficiently accurate to achieve the objective of our work. Furthermore, as discussed in detail later in this report, our methodology is sound and any inconsistencies between our finding and the findings of the HHS-OIG report, which was based on data from the fourth quarter of 2007, are largely due to significant fluctuations in drug prices over time. CMS also provided technical comments, which we incorporated as appropriate.

Background

Medicaid is a joint federal-state entitlement program that finances medical services for certain low-income adults and children.[25] While federal law generally requires 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

[24]The average retail pharmacy acquisition costs we used do not account for rebates and discounts that pharmacies may receive from wholesalers or manufacturers. We were unable to identify any data sources for these acquisition costs that account for rebates and discounts.

[25]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.

optional benefit that all state Medicaid programs have elected to include in their Medicaid benefit packages.

Medicaid Federal Upper Limits

FULs were established in 1987 as a cost-containment strategy to limit the amount that Medicaid could reimburse retail pharmacies for certain multiple-source outpatient prescription drugs.[26] CMS publishes a list of drugs that have FULs in the State Medicaid Manual. FULs are expressed per unit—for example, per tablet. As of September 2009, the list included approximately 740 multiple-source drugs.

CMS determines the FUL for a multiple-source outpatient prescription drug by grouping a drug's therapeutically equivalent versions 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), wholesale acquisition cost (WAC), and direct price (DP).[27] All 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 drug may be any one of these three prices. 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; the usual and customary charge[28] of the retail pharmacy that dispensed the drug; the FUL for the drug, if applicable; or the state's maximum allowable cost[29] (MAC) for the drug, if applicable. When the FUL for a drug is not the lowest of these four amounts, Medicaid typically reimburses pharmacies at a rate lower than the FUL.

[26]52 *Fed. Reg.* 28648 (July 31, 1987). Legislation was enacted in 1990 requiring the application of FULs. Pub. L. No. 101-508, § 4401(a)(3), 104 Stat. 1388, 1388-143, 151 (1990).

[27]AWP is the average of the list prices that the manufacturer suggests wholesalers charge pharmacies. WAC is the manufacturer's list price for wholesalers or other direct purchasers before any rebates, discounts, allowances, or other price concessions. 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.

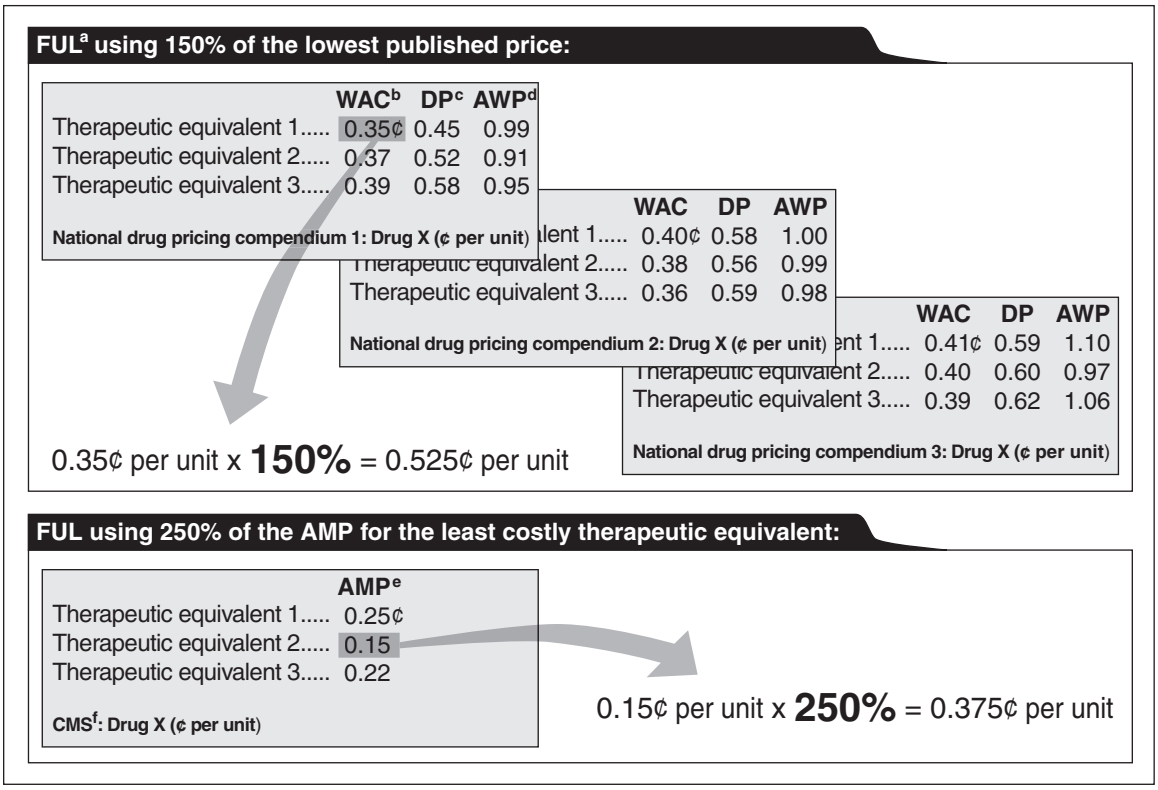
[28]The usual and customary charge for a drug is the full retail price that individuals without prescription drug coverage pay when purchasing drugs at a retail pharmacy.

[29]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 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 June 2009, 45 states administer MACs.

Deficit Reduction Act of 2005

The DRA methodology for setting FULs would require CMS to calculate FULs as 250 percent of the AMP for the least costly of a drug's therapeutically equivalent versions. AMP data are collected by CMS and are currently not publicly available. (Fig. 1 illustrates how Medicaid FULs are calculated using 150 percent of the lowest published price versus using 250 percent of the AMP for the least costly therapeutic equivalent.)

Figure 1: Illustration of FUL Methodology



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.

The DRA included additional provisions relating to prescription drugs. One provision changed the criteria under which FULs must be established. Under the current methodology, FULs must be established for multiple-source drugs with three or more therapeutically equivalent products. However, the DRA would require the establishment of FULs for multiple-source drugs with two or more therapeutically equivalent products. The DRA also included several changes relating to the calculation of AMP. For example, it required that prompt payment discounts be excluded when manufacturers calculate AMP.

Implementation of AMP-Based FULs

CMS issued a final rule in July 2007 to implement the AMP-based FUL provisions of the DRA. The final rule provides instructions for drug manufacturers in calculating and reporting AMPs, among other things. The final rule took effect in October 2007, which was the first month that drug manufacturers began reporting monthly AMP data to CMS.

However, the November 2007 lawsuit filed by the NACDS and NCPA claimed that the AMP rule would unlawfully change the methodology for reimbursement of pharmacies on the grounds that it was contrary to statute, among other things. In December 2007, the U.S. District Court for the District of Columbia issued a preliminary injunction ordering CMS not to implement the final rule to the extent that it affects Medicaid reimbursement rates for retail pharmacies. However, the preliminary injunction allowed the use of AMP as defined in the final rule for purposes of the Medicaid drug rebate program.[30] Therefore, drug manufacturers are continuing to report AMPs on a monthly and a quarterly basis in accordance with the provisions of the July 2007 rule and CMS is using these data for the purposes of the Medicaid drug rebate program. On July 15, 2008, MIPPA was enacted and prohibited CMS from taking any action before October 1, 2009, to implement the AMP-based FULs. As of October 1, 2009, the lawsuit was pending and the preliminary injunction remained in effect.

Median AMP-Based FULs Would Have Been Generally Lower Than Average Retail Pharmacy Acquisition Costs

Had AMP-based FULs been in place in the second quarter of 2008 they would have been lower than average retail pharmacy acquisition costs for most of the individual drugs in our sample and in the aggregate. However, pharmacies may be able to acquire therapeutically equivalent versions of most drugs at prices lower than the AMP-based FUL. Further, AMP-based FULs varied significantly throughout 2008 for about half the drugs in our sample.

For Most Individual Drugs in Our Sample, AMP-Based FULs Would Have Been Generally Lower Than Average Retail Pharmacy Acquisition Costs

The median AMP-based FULs that we calculated for the second quarter of 2008 would have been generally lower than average retail pharmacy acquisition costs for 54 of the 83 drugs in our sample. Of these 54 drugs, 44 drugs had median AMP-based FULs that would have been at least 25 percent below average retail pharmacy acquisition costs. However, more than a third of the drugs in our sample (29 of 83) had median AMP-based FULs equal to or greater than acquisition costs. (See encl. II for a list of the 54 drugs in our sample for which the median AMP-based FULs would have been below the average retail pharmacy acquisition

[30]Under the Medicaid drug rebate program, pharmaceutical manufacturers pay rebates to states for the drugs they purchase as a condition of participating in the state programs.

costs and the 29 drugs for which the median AMP-based FULs would have been above the average retail pharmacy acquisition costs.) While median AMP-based FULs would have been generally lower than acquisition costs across our entire sample of drugs, this difference was most pronounced for the 34 high-expenditure drugs in our sample, compared with the 32 high-utilization drugs and the 17 drugs that overlapped both categories. Our results were similar when we compared the monthly AMP-based FULs for April, May, and June of 2008 to acquisition costs for the second quarter of 2008.

These findings differ somewhat from the findings in our 2006 report, which found that less than a quarter of the drugs in our sample (18 of the 77) had AMP-based FULs equal to or greater than acquisition costs. The outlier provision included in CMS's July 2007 final rule—and therefore not taken into account in our 2006 report—increased the number of drugs for which AMP-based FULs would have been sufficient to cover acquisition costs. Without the outlier provision, the number of drugs with AMP-based FULs sufficient to cover acquisition costs would have been 25 drugs instead of 29 drugs.

High-Expenditure Drugs

For 29 of the 34 high-expenditure drugs in our sample, the median AMP-based FULs we calculated for the second quarter of 2008 would have been lower than the average retail pharmacy acquisition costs for this period. The AMP-based FULs for 25 of these 29 drugs would have been at least 25 percent below average retail pharmacy acquisition costs. (See fig. 2.)

Figure 2: Comparison of Median AMP-Based FULs and Average Retail Pharmacy Acquisition Costs for 34 High-Expenditure Outpatient Drugs in Medicaid, Second Quarter 2008

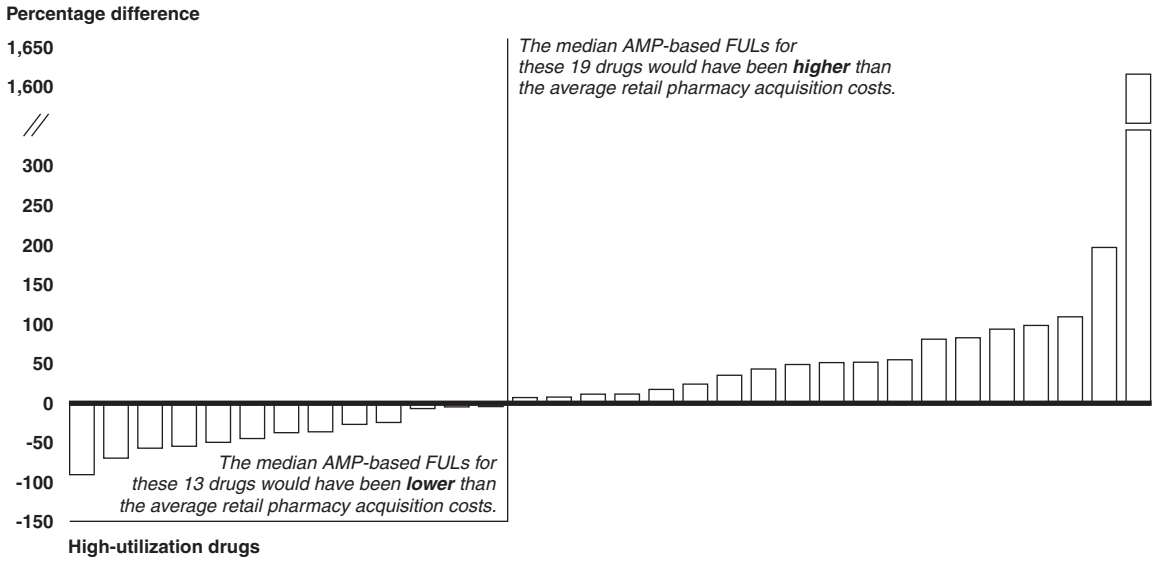
Source: GAO analysis of utilization and FUL data from CMS and acquisition cost data from IMS Health.

Note: The average retail pharmacy acquisition cost data that we obtained from IMS Health do not account for rebates and discounts that pharmacies may receive from wholesalers or manufacturers, if they are not reflected in invoice prices. We were unable to identify any data sources of acquisition costs for multiple-source outpatient prescription drugs that account for rebates and discounts.

High-Utilization Drugs

Conversely, only 13 of the 32 high-utilization drugs in our sample had median AMP-based FULs that would have been lower than the average retail pharmacy acquisition costs. The AMP-based FULs for 9 of these 13 drugs would have been at least 25 percent below average retail pharmacy acquisition costs. (See fig. 3).

Figure 3: Comparison of Median AMP-Based FULs and Average Retail Pharmacy Acquisition Costs for 32 High-Utilization Outpatient Drugs in Medicaid, Second Quarter 2008



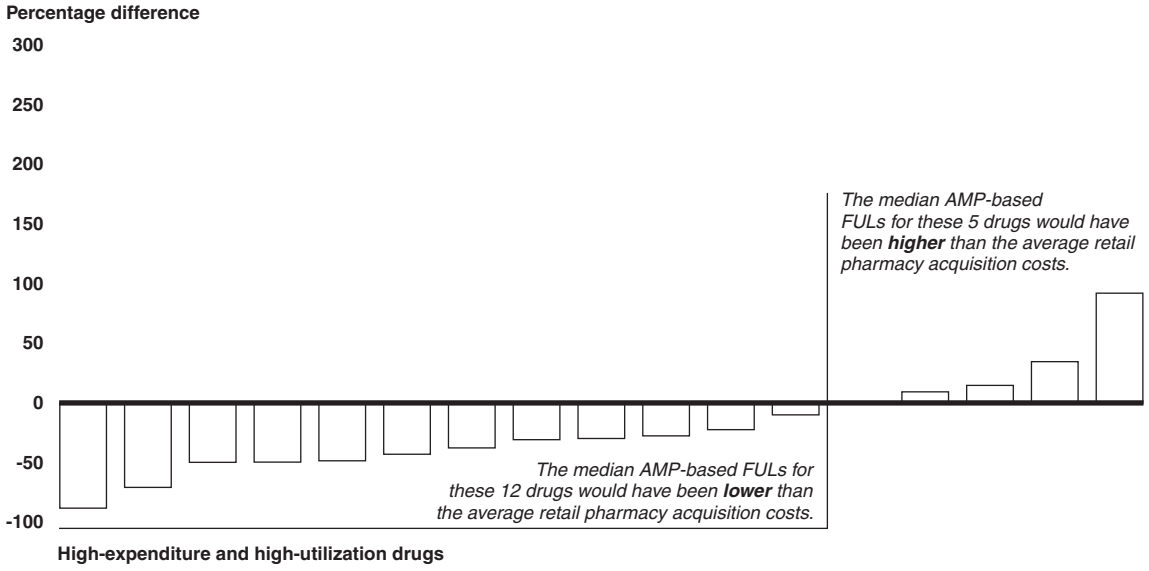
Source: GAO analysis of utilization and FUL data from CMS and acquisition cost data from IMS Health.

Note: The average retail pharmacy acquisition cost data that we obtained from IMS Health do not account for rebates and discounts that pharmacies may receive from wholesalers or manufacturers, if they are not reflected in invoice prices. We were unable to identify any data sources of acquisition costs for multiple-source outpatient prescription drugs that account for rebates and discounts.

High-Expenditure and High-Utilization Drugs

For 12 of the 17 drugs in our sample that overlapped both categories, the median AMP-based FULs we calculated would have been below average retail pharmacy acquisition costs for the second quarter of 2008. Further, the median AMP-based FULs for 10 of these drugs would have been at least 25 percent below average retail pharmacy acquisition costs. (See fig. 4.)

Figure 4: Comparison of Median AMP-Based FULs and Average Retail Pharmacy Acquisition Costs for 17 Outpatient Drugs That Were Both High-Expenditure and High-Utilization in Medicaid, Second Quarter 2008



Source: GAO analysis of utilization and FUL data from CMS and acquisition cost data from IMS Health.

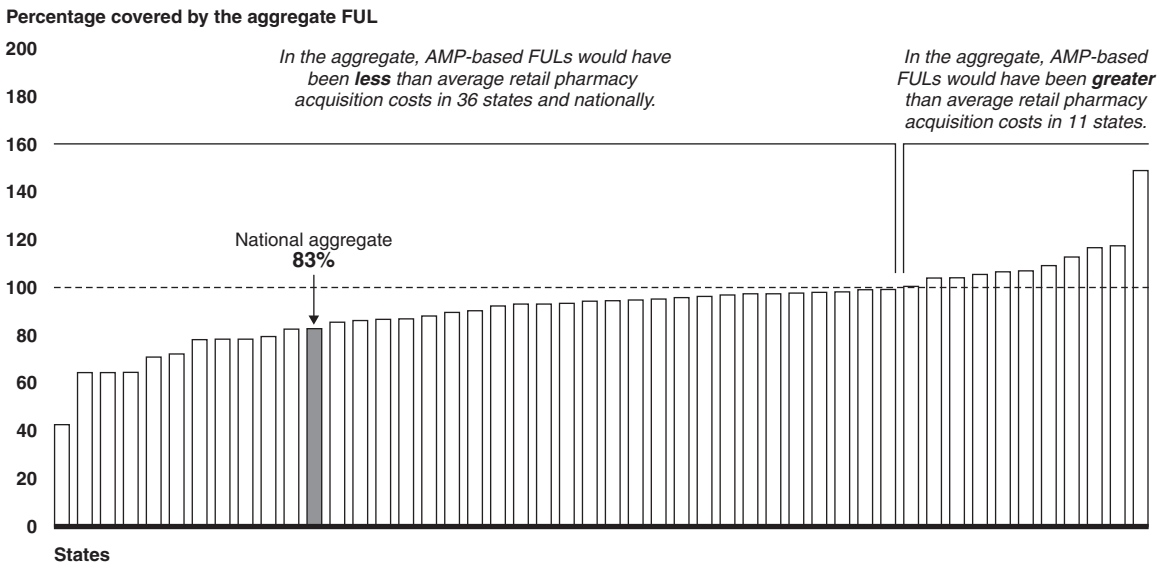
Note: The average retail pharmacy acquisition cost data that we obtained from IMS Health do not account for rebates and discounts that pharmacies may receive from wholesalers or manufacturers, if they are not reflected in invoice prices. We were unable to identify any data sources of acquisition costs for multiple-source outpatient prescription drugs that account for rebates and discounts.

Median AMP-based FULs Would Have Been Lower Than Acquisition Costs in the Aggregate

In the aggregate, for our sample of 83 drugs, the median AMP-based FULs we calculated for the second quarter of 2008 would have been 17 percent less than the average retail pharmacy acquisition costs for the same period, when weighted by drug utilization at the national level. However, this difference varied significantly from state to state.[31] Aggregate median AMP-based FULs would have been between 57 percent less than and 49 percent greater than the aggregate acquisition costs, when weighted by drug utilization in each individual state. In 11 states, the aggregate AMP-based FULs covered at least 100 percent of aggregate acquisition costs, and in another 19 states, the aggregate AMP-based FULs covered more than 90, but less than 100 percent. In 10 other states, however, the aggregate AMP-based FULs covered 80 percent or less. (See fig. 5.) (See encl. III for a comparison in the aggregate of median AMP-based FULs to average retail pharmacy acquisition costs for the 83 drugs in our sample for each state.)

[31]At the time we requested them from CMS, drug utilization data were not available for the second quarter of 2008 for Alabama, Arizona, Rhode Island, and Tennessee, and the U.S. territories of American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the Virgin Islands. Because we lacked utilization data for these states and territories, they have been excluded from our aggregate analyses.

Figure 5: Comparison, in the Aggregate for 83 Drugs, of Median AMP-based FULs to Average Retail Pharmacy Acquisition Costs, Second Quarter 2008



Source: GAO analysis of utilization and FUL data from CMS and acquisition cost data from IMS Health.

Note: The average retail pharmacy acquisition cost data that we obtained from IMS Health do not account for rebates and discounts that pharmacies may receive from wholesalers or manufacturers, if they are not reflected in invoice prices. We were unable to identify any data sources of acquisition costs for multiple-source outpatient prescription drugs that account for rebates and discounts. We used national pharmacy acquisition costs to conduct this analysis because acquisition cost data were not available from IMS Health at the state level.

At the time we requested them from CMS, drug utilization data were not available for the second quarter of 2008 for Alabama, Arizona, Rhode Island, and Tennessee and the U.S. territories of American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the Virgin Islands. Because we lacked utilization data for these states and territories, they have been excluded from our aggregate analyses.

Pharmacies May Be Able to Acquire Therapeutically Equivalent Versions of Most Drugs at Costs Below Their FULs

For 64 of the 83 drugs in our sample, or 77 percent, we found that at least one therapeutically equivalent version had average retail pharmacy acquisition costs that would have been below the median AMP-based FUL in the second quarter of 2008. (See table 1.) For 38 of these drugs, at least half of the Medicaid utilization during this quarter was for therapeutically equivalent versions for which acquisition costs would have been less than the median AMP-based FUL, including 23 drugs for which at least 90 percent of Medicaid utilization was for such versions. Across all 83 drugs, 43 percent of each drug's Medicaid utilization, on average, was for therapeutically equivalent versions for which acquisition costs would have been below the AMP-based FUL. (See encl. I for the percentage of utilization accounted for by therapeutically equivalent versions of each drug with average pharmacy acquisition costs that would have been below the AMP-based FUL.)

Table 1: Percentage of Each Drug's Medicaid Utilization That Is Accounted for by Therapeutic Equivalents with Average Retail Pharmacy Acquisition Costs That Would Have Been Below the Median AMP-based FULs, Second Quarter 2008

Percentage of Medicaid utilization	Number of drugs
90.0 percent – 100.0 percent	23
75.0 percent – 89.9 percent	6
50.0 percent – 74.9 percent	9
25.0 percent – 49.9 percent	5
0.1 percent – 24.9 percent	21
Zero percent	19
Total	**83**

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

Note: The average retail pharmacy acquisition cost data that we obtained from IMS Health do not account for rebates and discounts that pharmacies may receive from wholesalers or manufacturers, if they are not reflected in invoice prices. We were unable to identify any data sources of acquisition costs for multiple-source outpatient prescription drugs that account for rebates and discounts.

In addition, of the 54 drugs in our sample with average retail pharmacy acquisition costs that would have been above the median AMP-based FULs, 35 had one or more therapeutically equivalent versions with average retail pharmacy acquisition costs that would have been below the FUL, which accounted for an average of 27 percent of each drug's Medicaid utilization. Therefore, to the extent that the lower cost, therapeutically equivalent versions of these drugs are readily available to pharmacies—and that pharmacies choose to acquire them—it may be possible for pharmacies to reduce their costs for many of these drugs to levels below the FUL by increasing their use of lower-priced therapeutic equivalents.

We also found that the high-utilization drugs in our sample were more likely than the high-expenditure drugs to have therapeutically equivalent versions with average retail pharmacy acquisition costs that would have been below their FULs. Specifically, for 22 of 32 (69 percent) high-utilization drugs, at least half of the Medicaid utilization during the second quarter of 2008 was accounted for by therapeutically equivalent versions with acquisition costs that would have been below their median AMP-based FULs, while this was true for only 10 of 34 (29 percent) high-expenditure drugs and 6 of 17 (35 percent) of the drugs that were both high-expenditure and high-utilization.

AMP-Based FULs Varied Significantly for Some Drugs in 2008, Affecting the Relationship Between FULs and Acquisition Costs

For 38 drugs in our sample of 83 drugs—or 46 percent—monthly AMP-based FULs varied by at least 100 percent throughout 2008, which affected the relationship between FULs and average retail pharmacy acquisition costs and in some cases affected whether AMP-based FULs would have been higher or lower than acquisition costs in each month. For example, for 16 of the 83 drugs in our sample, we found that the monthly variation in AMP-based FULs would have resulted in the FUL for a drug exceeding the average retail pharmacy acquisition cost in at least one month during the second quarter of 2008 and falling below the acquisition cost in another month during that same quarter.

While monthly variation in AMP-based FULs was partly due to monthly increases or decreases in the AMPs used to set the FULs, missing AMP data in each month of 2008 also accounted for some variation. Although CMS requires drug manufacturers to submit monthly AMP data no later than 30 days after the end of the prior month, in 2008, manufacturers did not report AMP data to CMS for an average of 11 percent of the therapeutically equivalent versions of the 83 drugs in our sample in each month. We found that missing AMP data affected the AMP-based FULs because CMS calculates them monthly, generally using the lowest AMP for each drug subject to a FUL.[32] Therefore, if a manufacturer reports the AMP for the lowest-priced therapeutically equivalent version of a drug in one month but does not report it in a subsequent month, the FUL for the second month will be based on the AMP for a different version of that drug, which may result in a change in the FUL between the two months.

The monthly variation in AMP-based FULs may make it difficult for states to reimburse pharmacies in accordance with AMP-based FULs, because they may need to adjust their reimbursement rates on a monthly basis in order to reimburse pharmacies the amounts corresponding to the FULs. CMS officials told us that, if the agency is permitted to implement AMP-based FULs, CMS will assist states in preparing to use FULs that are updated monthly. The officials also stated that public disclosure of AMP data along with the implementation of AMP-based FULs should lessen the monthly variation in the FULs because manufacturers would likely increase their compliance with the monthly AMP reporting requirement. CMS officials believe that manufacturers would increase compliance because manufacturers who do not comply with the requirement could be easily identified.

Agency Comments and Our Evaluation

HHS provided us with CMS's written comments on a draft of this report. The agency's comments are reprinted in enclosure IV. CMS disagreed with our finding that if AMP-based FULs had been in place in the second quarter of 2008, they would have been lower than average retail pharmacy acquisition costs for most of the 83 drugs in our sample and in the national aggregate. In particular, CMS expressed concerns about our data source used to estimate average retail pharmacy acquisition costs, including that it does not take into account discounts and rebates that drug manufacturers and wholesalers may provide to retail pharmacies. CMS also expressed concerns about our methodology and inconsistencies between our finding and the findings of an HHS-OIG report. However, as we indicate in this report and address below, data on discounts and rebates pharmacies receive are not readily available. We used the most complete, accurate, and verifiable data source available at the time of our analysis to estimate average retail pharmacy acquisition costs. We believe that these data are sufficiently accurate to achieve the objective of our work. Furthermore, as discussed below, our methodology is sound and any inconsistencies between our finding and the findings of the HHS-OIG report are largely due to significant fluctuations in drug prices over time.

CMS questioned the validity of our estimation of national average retail pharmacy acquisition costs because we were unable to account for certain discounts and rebates retail pharmacies may receive from wholesalers and drug manufacturers, if they are not accounted for in

[32]42 C.F.R. § 447.514(c)(2)(2008). Under the outlier provision, if the lowest AMP is less than 40 percent of the second-lowest AMP, CMS uses the second-lowest AMP for a multiple-source drug to calculate the AMP-based FUL. The outlier provision only applies to multiple-source drugs with three or more therapeutically equivalent versions.

invoice prices. In our report, we state that the IMS Health data did not account for such discounts and rebates, and we identified this as a limitation of our analysis. Had we been able to fully include discounts and rebates in our estimation of average retail pharmacy acquisition costs, these discounts and rebates would had to have averaged at least 17 percent of the average retail pharmacy acquisition cost in order to offset the difference between AMP-based FULs and pharmacy acquisition costs in the aggregate.[33]

Further, we know of no data sources of national average pharmacy acquisition costs for multiple-source outpatient prescription drugs that fully account for discounts and rebates. CMS stated that an HHS-OIG report, which the OIG shared with us because it has not been publicly issued as of November 2009, was able to partially account for discounts and rebates.[34] However, as CMS acknowledges, the data on which the OIG relied also had limitations. Specifically, only half of the drug distributors that responded to the OIG's survey reported data on discounts and rebates. The OIG collected its pharmacy acquisition cost data for the 50 drugs in its sample from a selection of 4 drug distributors. Two of the 4 drug distributors did not report data on discounts and rebates.[35] Moreover, accounting for discounts and rebates is difficult because retail pharmacies negotiate their discounts and rebates based on various factors and can negotiate them on a manufacturer's entire line of products rather than per drug.

CMS also questioned the validity of the pharmacy acquisition cost data that we acquired from IMS Health, because of significant variation between these data and the pharmacy acquisition cost data used by the OIG. While we cannot speak to the validity of the OIG's survey data because we did not evaluate it, we used the most complete and accurate data available at the time of our analysis to estimate average retail pharmacy acquisition costs, as stated previously. Furthermore, we do not believe that the variation between the two data sources indicates that either is invalid because significant variation in both pharmacy acquisition costs and AMPs can be expected to occur over time, and the OIG data were from the fourth quarter of 2007 and therefore 6 months older than our data, on average. To illustrate this, we analyzed variation in AMP data for each therapeutically equivalent version of the 83 drugs in our sample across 2008. We found that AMPs, which represent actual transaction prices between drug manufacturers and wholesalers, varied by as much as 1,100 percent throughout 2008 for individual therapeutically equivalent versions of drugs and that 24 percent of therapeutically equivalent versions of the drugs in our sample varied by more than 100 percent during that year. In addition, we compared average retail pharmacy acquisition costs between the first quarter of 2006 and the second quarter of 2008 for the therapeutically equivalent versions of drugs that were included in both our previous report on AMP-based

[33]While the average amount of rebates for pharmacies is unknown, rebates in other parts of the pharmaceutical industry are considerably less than 17 percent. For example, in a 2003 report, we found that the range of rebates paid by pharmacy benefit managers to three health plans participating in the Federal Employees' Health Benefit Program ranged from 3 to 9 percent. See GAO, *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefits Managers on Health Plans, Enrollees, and Pharmacies*, GAO-03-196 (Washington, D.C.: Jan. 10, 2003). In addition, the statutory rebate for drug manufacturers to reimburse state Medicaid programs for generic drugs is 11 percent of AMP.

[34]We reviewed this report and discussed it with OIG officials. However, we did not evaluate the OIG's data sources.

[35]Entities may be reluctant to disclose drug pricing data, because doing so may place them at a competitive disadvantage.

FULs and this report.[36] We found that the pharmacy acquisition costs in the second quarter of 2008 were between 97 percent lower and 993 percent higher than in the first quarter of 2006. Consequently, our finding should not be compared directly to the OIG's findings, because the two studies were conducted using data from different time periods.

CMS also stated that the OIG report provides a more accurate comparison of AMP-based FULs to pharmacy acquisition costs, because the OIG was able to analyze the lowest pharmacy acquisition cost among all transactions. While we did not conduct our comparison based on the lowest pharmacy acquisition cost, our report includes an analysis of the therapeutically equivalent versions of each drug in our sample that pharmacies may be able to acquire at a cost below AMP-based FULs. As we state in our report, we found that for 64 drugs or 77 percent of the drugs in our sample, at least one therapeutically equivalent version had average retail pharmacy acquisition costs that would have been below the median AMP-based FUL in the second quarter of 2008. However, in many cases, pharmacies are not currently purchasing these versions.

CMS stated that we did not release source data or evidence of how IMS Health arrived at the acquisition costs used in our comparison. We clarified our report to explain that on a monthly basis, IMS Health collects data on drugs purchased by retail pharmacies from about 100 drug manufacturers and about 500 distribution centers. These manufacturers and distribution centers provide data on the number of units sold, and a portion of them provide data on actual retail pharmacy acquisition costs. For those manufacturers and distribution centers that only provide data on the number of units sold, IMS Health estimates retail pharmacy acquisition costs based on the actual acquisition cost data it was able to obtain from others. Once IMS Health determines average retail pharmacy acquisition costs from data it collects, it projects these data to represent national average retail pharmacy acquisition costs using a model that is reviewed monthly. In addition, IMS Health conducts detailed data reliability assessments, which include comparing monthly data from drug manufacturers and distribution centers to data from the prior month and the prior year in order to ensure consistency and comparing reported pricing data against published prices to ensure that the data IMS Health receive are in fact transaction prices rather than the published prices. Consistent with our data use agreement with IMS Health, we did not include the acquisition cost data used in our analysis in our report or otherwise disclose them to CMS because, while they are commercially available, they are proprietary.

CMS stated that it was concerned about our use of median AMP-based FUL data to compare AMP-based FULs to pharmacy acquisition costs because AMP-based FULs are calculated on a monthly basis. We used the median AMP-based FULs for the second quarter of 2008 because CMS reports utilization data on a quarterly basis and in order to mitigate the effects of monthly variation in AMP-based FULs on this comparison. As we stated in our report, for 16 of the 83 drugs in our sample, monthly variation in the AMP-based FULs was significant enough to have resulted in the FUL for a drug exceeding the average retail pharmacy acquisition cost in at least one month during the second quarter of 2008 and falling below the acquisition cost in another month during that same quarter. Comparing the data on a monthly basis would have increased the risk that monthly variation in AMP-based FULs would have inappropriately affected the results of our analysis.

[36]We used average retail pharmacy acquisition cost data from the first quarter of 2006 for this analysis because our previous report comparing AMP-based FULs to average retail pharmacy acquisition costs was based on data from that quarter. See GAO, *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*, GAO-07-239R (Washington, D.C.: Dec. 22, 2006).

CMS also stated that our sample of 83 drugs is not a true reflection of all drugs that would have been subject to AMP-based FULs in the second quarter of 2008 because it only included 6 percent of such drugs. As we stated in our report, our sample of drugs is not representative of all drugs that would have been subject to AMP-based FULs. However, our sample represented 64 percent of total Medicaid utilization and 52 percent of total Medicaid expenditures for drugs that would have been subject to AMP-based FULs in the second quarter of 2008.

CMS noted that our analysis did not address how average retail pharmacy acquisition costs compare to current FULs that are based on published prices. A comparison of average retail pharmacy acquisition costs to current FULs was outside the scope of this report. Furthermore, this comparison has been well-documented by the HHS-OIG and others.[37] In addition, CMS noted that our analysis did not address existing state cost-containment efforts, such as MAC programs, to reduce Medicaid reimbursements for outpatient prescription drugs. While the relationship between AMP-based FULs and state Medicaid cost-containment efforts is a valid area of analysis, this issue was also beyond the scope of our report.

In response to our concerns about monthly variation in the AMP-based FULs, CMS noted that it is aware of monthly fluctuations in AMP-based FULs and that it is considering measures to ensure that pharmacy reimbursement is fair and that drug manufacturers report AMP data in a timely manner. The agency also noted that public disclosure of AMP data would help bring transparency to drug prices and help ensure that pharmacies can determine which therapeutically equivalent version of each drug could be acquired at a cost below its AMP-based FULs.

CMS also provided technical comments, which we incorporated as appropriate.

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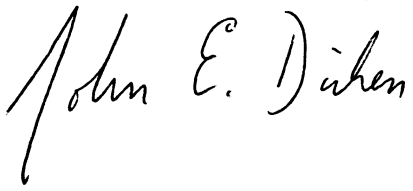
As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days after its issue date. At that time, we will send copies to the Secretary of Health and Human Services and interested congressional committees. The report will also be available at no charge on GAO's Web site at http://www.gao.gov.

[37]For example, a 2007 HHS-OIG report found that for 23 out of 25 selected drugs, FULs that are based on published prices were more than double the average pharmacy acquisition costs. See, HHS OIG, *Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program*, OEI-03-06-00400 (Philadelphia, Pa.: June 2007).

If you or your staff have any questions regarding this report, please contact me at (202) 512-7114 or dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff members who made key contributions to this report are listed in enclosure V.

Sincerely yours,



John E. Dicken
Director, Health Care

Enclosure I

The 83 Medicaid Outpatient Prescription Drugs GAO Reviewed, Sample Category into which Each Drug Falls, and Percentage of Each Drug's Medicaid Utilization for which the Average Pharmacy Acquisition Cost Would Have Been Below the Median AMP-Based FUL, Second Calendar Quarter of 2008

Drug name and strength	Dosage form	Sample category into which each drug falls (high utilization, high expenditure, or high utilization and high expenditure)	Percentage of each drug's Medicaid utilization that was accounted for by therapeutically equivalent versions with an average pharmacy acquisition cost that would have been below the median AMP-based FUL
Acetaminophen; hydrocodone bitartrate 500mg/15ml; 7.5mg/15ml	Solution	High utilization	2.3
Acetaminophen; hydrocodone bitartrate 325mg; 10mg	Tablet	High utilization and high expenditure	10.0
Acetaminophen; hydrocodone bitartrate 500mg; 10mg	Tablet	High utilization and high expenditure	99.5
Acetaminophen; hydrocodone bitartrate 500mg; 5mg	Tablet	High utilization	97.2
Acetaminophen; oxycodone hydrochloride 325mg; 5mg	Tablet	High utilization	85.7
Albuterol sulfate 0.083%	Solution	High utilization and high expenditure	100.0
Alendronate sodium 70mg	Tablet	High expenditure	54.1
Alprazolam 0.25mg	Tablet	High utilization	0.0
Alprazolam 0.5mg	Tablet	High utilization	0.0
Alprazolam 1mg	Tablet	High utilization	0.0
Amlodipine besylate 10mg	Tablet	High expenditure	0.0
Amlodipine besylate 5mg	Tablet	High expenditure	3.8
Amoxicillin 125mg/5ml	Suspension	High utilization	99.4
Amoxicillin 250mg/5ml	Suspension	High utilization	99.7
Amoxicillin 400mg/5ml	Suspension	High utilization and high expenditure	79.6
Amoxicillin; clavulanic acid 400mg/5ml; 57mg/5ml	Suspension	High utilization and high expenditure	54.4
Amoxicillin; clavulanic acid 600mg/5ml; 42.9mg/5ml	Suspension	High utilization and high expenditure	7.8
Amoxicillin; clavulanic acid 875mg; 125mg	Tablet	High expenditure	93.1
Azithromycin 100mg/5ml	Suspension	High expenditure	72.0
Azithromycin 200mg/5ml	Suspension	High expenditure	0.0
Azithromycin 250mg	Tablet	High expenditure	35.0
Bupropion hydrochloride 150mg	Extended release tablet	High expenditure	1.2
Bupropion hydrochloride 300mg	Extended release tablet	High expenditure	55.0

Drug name and strength	Dosage form	Sample category into which each drug falls (high utilization, high expenditure, or high utilization and high expenditure)	Percentage of each drug's Medicaid utilization that was accounted for by therapeutically equivalent versions with an average pharmacy acquisition cost that would have been below the median AMP-based FUL
Carbamazepine 100mg/5ml	Suspension	High utilization	99.8
Cefdinir 300mg	Capsule	High expenditure	14.6
Cefdinir 125mg/5ml	Suspension	High expenditure	86.2
Cefdinir 250mg/5ml	Suspension	High utilization and high expenditure	65.1
Cephalexin 250mg/5ml	Suspension	High utilization	99.4
Chlorhexidine gluconate 0.12%	Solution	High utilization	77.2
Clonazepam 0.5mg	Tablet	High utilization	7.4
Clonazepam 1mg	Tablet	High utilization and high expenditure	41.0
Clonidine hydrochloride 0.1mg	Tablet	High utilization	99.7
Clozapine 100mg	Tablet	High expenditure	91.4
Codeine phosphate; promethazine hydrochloride 10mg/5ml; 6.25mg/5ml	Syrup	High utilization	98.7
Cyclobenzaprine hydrochloride 10mg	Tablet	High utilization	0.0
Desmopressin acetate 0.2mg	Tablet	High expenditure	0.0
Dextromethorphan hydrobromide; promethazine hydrochloride 15mg/5ml; 6.25mg/5ml	Syrup	High utilization	100.0
Diazepam 10mg	Tablet	High utilization	99.9
Diphenhydramine hydrochloride 12.5mg/5ml	Elixir	High utilization	100.0
Fentanyl 100mcg	Film	High expenditure	0.0
Fentanyl 50mcg/hr	Film	High expenditure	0.0
Fentanyl 75mcg/hr	Film	High expenditure	0.0
Fluoxetine hydrochloride 20mg	Capsule	High utilization	0.3
Fluticasone propionate 0.05mg	Spray	High expenditure	0.0
Folic acid 1mg	Tablet	High utilization	0.0
Gabapentin 300mg	Capsule	High utilization and high expenditure	0.7
Gabapentin 600mg	Tablet	High expenditure	0.0
Gabapentin 800mg	Tablet	High expenditure	4.7
Griseofulvin microcrystalline 125mg/5ml	Suspension	High utilization and high expenditure	7.0
Hydrochlorothiazide 25mg	Tablet	High utilization	0.0
Ibuprofen 100mg/5ml	Suspension	High utilization	99.9
Ibuprofen 600mg	Tablet	High utilization	99.9
Ibuprofen 800mg	Tablet	High utilization	99.9
Lactulose 10gm/15ml	Solution	High utilization	99.3
Lamotrigine 25mg	Chewable tablet	High expenditure	100.0

Drug name and strength	Dosage form	Sample category into which each drug falls (high utilization, high expenditure, or high utilization and high expenditure)	Percentage of each drug's Medicaid utilization that was accounted for by therapeutically equivalent versions with an average pharmacy acquisition cost that would have been below the median AMP-based FUL
Lorazepam 0.5mg	Tablet	High utilization	0.4
Lorazepam 1mg	Tablet	High utilization and high expenditure	3.0
Medroxyprogesterone acetate 150mg/ml	Injectable	High expenditure	42.7
Metformin hydrochloride 500mg	Tablet	High utilization and high expenditure	0.0
Methadone hydrochloride 10mg	Tablet	High utilization	99.3
Metoclopramide hydrochloride 5mg/5ml	Solution	High utilization	58.4
Mupirocin 2%	Ointment	High expenditure	97.8
Nystatin 100000u/ml	Suspension	High utilization	74.0
Ofloxacin 0.3%	Solution/drops (ophthalmic)	High expenditure	58.8
Ofloxacin 0.3%	Solution/drops (otic)	High expenditure	0.4
Omeprazole 20mg	Delayed release capsule	High expenditure	20.8
Oxcarbazepine 300mg	Tablet	High expenditure	0.1
Oxcarbazepine 600mg	Tablet	High expenditure	0.1
Pantoprazole sodium 40mg	Delayed release tablet	High expenditure	100.0
Paroxetine hydrochloride 20mg	Tablet	High expenditure	17.9
Phenytoin sodium 100mg extended	Capsule	High utilization and high expenditure	0.5
Polyethylene glycol 3350 17gm/scoopful	Solution	High utilization and high expenditure	0.0
Ranitidine hydrochloride 15mg/ml	Syrup	High utilization and high expenditure	0.0
Ranitidine hydrochloride 150mg	Tablet	High utilization	80.5
Ribavirin 200mg	Capsule	High expenditure	28.3
Sertraline hydrochloride 100mg	Tablet	High utilization and high expenditure	0.1
Sertraline hydrochloride 50mg	Tablet	High expenditure	0.0
Simvastatin 20mg	Tablet	High expenditure	0.0
Simvastatin 40mg	Tablet	High expenditure	0.6
Tramadol hydrochloride 50mg	Tablet	High utilization and high expenditure	73.2
Triamcinolone acetonide 0.1%	Cream	High utilization	79.3
Valproic acid 250mg/5ml	Syrup	High utilization	94.1
Zolpidem tartrate 10mg	Tablet	High expenditure	37.0

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

Notes: Our sample contained 83 multiple-source outpatient prescription drugs for the second quarter of 2008, which comprised 32 drugs that were in the top 50 for Medicaid utilization, 34 drugs that were in the top 50 for Medicaid expenditures, and 17 drugs that were in the top 50 for both utilization and expenditures. Dispensing fees were excluded when calculating Medicaid expenditures.

The average retail pharmacy acquisition cost data that we obtained from IMS Health do not account for rebates and discounts that pharmacies may receive from wholesalers or manufacturers, if they are not reflected in invoice prices. We were unable to identify any data sources of acquisition costs for multiple-source outpatient prescription drugs that account for rebates and discounts.

Enclosure II

Comparison of Average Retail Pharmacy Acquisition Costs to Median Average Manufacturer Price (AMP)-Based Federal Upper Limits (FUL) for the 83 Medicaid Outpatient Prescription Drugs GAO Reviewed, Second Quarter of 2008

Drugs with AMP-based FULs that would have been *above* the average retail pharmacy acquisition cost	Drugs with AMP-based FULs that would have been *below* the average retail pharmacy acquisition cost
• Acetaminophen; hydrocodone bitartrate 500mg; 10mg (tablet)	• Acetaminophen; hydrocodone bitartrate 500mg/15ml; 7.5mg/15ml (solution)
• Acetaminophen; hydrocodone bitartrate 500mg; 5mg (tablet)	• Acetaminophen; hydrocodone bitartrate 325mg; 10mg (tablet)
• Acetaminophen; oxycodone hydrochloride 325mg; 5mg (tablet)	• Alendronate sodium 70mg (tablet)
• Albuterol sulfate 0.083% (solution)	• Alprazolam 0.25mg (tablet)
• Amoxicillin 125mg/5ml (suspension)	• Alprazolam 0.5mg (tablet)
• Amoxicillin 250mg/5ml (suspension)	• Alprazolam 1mg (tablet)
• Amoxicillin 400mg/5ml (suspension)	• Amlodipine besylate 10mg (tablet)
• Amoxicillin; clavulanic acid 400mg/5ml; 57mg/5ml (suspension)	• Amlodipine besylate 5mg (tablet)
• Carbamazepine 100mg/5ml (suspension)	• Amoxicillin; clavulanic acid 600mg/5ml; 42.9mg/5ml (suspension)
• Cefdinir 125mg/5ml (suspension)	• Amoxicillin; clavulanic acid 875mg; 125mg (tablet)
• Cefdinir 250mg/5ml (suspension)	• Azithromycin 100mg/5ml (suspension)
• Cephalexin 250mg/5ml (suspension)	• Azithromycin 200mg/5ml (suspension)
• Chlorhexidine gluconate 0.12% (solution)	• Azithromycin 250mg (tablet)
• Clonidine hydrochloride 0.1mg (tablet)	• Bupropion hydrochloride 150mg (extended release tablet)
• Clozapine 100mg (tablet)	• Bupropion hydrochloride 300mg (extended release tablet)
• Codeine phosphate; promethazine hydrochloride 10mg/5ml; 6.25mg/5ml (syrup)	• Cefdinir 300mg (capsule)
• Dextromethorphan hydrobromide; promethazine hydrochloride 15mg/5ml;6.25mg/5ml (syrup)	• Clonazepam 0.5mg (tablet)
• Diazepam 10mg (tablet)	• Clonazepam 1mg (tablet)
• Diphenhydramine hydrochloride 12.5mg/5ml (elixir)	• Cyclobenzaprine hydrochloride 10mg (tablet)
• Ibuprofen 100mg/5ml (suspension)	• Desmopressin acetate 0.2mg (tablet)
• Ibuprofen 600mg (tablet)	• Fentanyl 100mcg (film)
• Ibuprofen 800mg (tablet)	• Fentanyl 50mcg/hr (film)
• Lactulose 10gm/15ml (solution)	• Fentanyl 75mcg/hr (film)
• Lamotrigine 25mg (chewable tablet)	• Fluoxetine hydrochloride 20mg (capsule)
• Methadone hydrochloride 10mg (tablet)	• Fluticasone propionate 0.05mg (spray)
• Metoclopramide hydrochloride 5mg/5ml (solution)	• Folic acid 1mg (tablet)
• Mupirocin 2% (ointment)	• Gabapentin 300mg (capsule)
• Pantoprazole sodium 40mg (delayed release tablet)	• Gabapentin 600mg (tablet)
• Triamcinolone acetonide 0.1% (cream)	• Gabapentin 800mg (tablet)
	• Griseofulvin microcrystalline 125mg/5ml (suspension)
	• Hydrochlorothiazide 25mg (tablet)
	• Lorazepam 0.5mg (tablet)
	• Lorazepam 1mg (tablet)
	• Medroxyprogesterone acetate 150mg/ml (injectable)

Drugs with AMP-based FULs that would have been *above* the average retail pharmacy acquisition cost	Drugs with AMP-based FULs that would have been *below* the average retail pharmacy acquisition cost
	• Metformin hydrochloride 500mg (tablet) • Nystatin 100000u/ml (suspension) • Ofloxacin 0.3% (solution/drops – ophthalmic) • Ofloxacin 0.3% (solution/drops – otic) • Omeprazole 20mg (delayed release capsule) • Oxcarbazepine 300mg (tablet) • Oxcarbazepine 600mg (tablet) • Paroxetine hydrochloride 20mg (tablet) • Phenytoin sodium 100mg extended (capsule) • Polyethylene glycol 3350 17gm/scoopful (solution) • Ranitidine hydrochloride 15mg/ml (syrup) • Ranitidine hydrochloride 150mg (tablet) • Ribavirin 200mg (capsule) • Sertraline hydrochloride 100mg (tablet) • Sertraline hydrochloride 50mg (tablet) • Simvastatin 20mg (tablet) • Simvastatin 40mg (tablet) • Tramadol hydrochloride 50mg (tablet) • Valproic acid 250mg/5ml (syrup) • Zolpidem tartrate 10mg (tablet)

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

Notes: Our sample contained 83 multiple-source outpatient prescription drugs for the second quarter of 2008, which comprised 32 drugs that were in the top 50 for Medicaid utilization, 34 drugs that were in the top 50 for Medicaid expenditures, and 17 drugs that were in the top 50 for both utilization and expenditures. Dispensing fees were excluded when calculating Medicaid expenditures.

The average retail pharmacy acquisition cost data that we obtained from IMS Health do not account for rebates and discounts that pharmacies may receive from wholesalers or manufacturers, if they were not included in invoice prices. We were unable to identify any data sources of these acquisition costs that account for rebates and discounts.

Enclosure III

Comparison in the Aggregate of Median AMP-based FULs to Average Retail Pharmacy Acquisition Costs for 83 Drugs, Second Quarter 2008

State[a]	Percentage of acquisition costs[b] that would have been covered by the AMP-based FUL, in the aggregate, for 83 drugs	Percent of Medicaid utilization represented by 83 drugs
Alaska	72.3	56.1
Arkansas	96.4	57.8
California	42.7	54.9
Colorado	105.6	55.3
Connecticut	94.4	53.9
Delaware	64.5	56.6
District Of Columbia	71.0	43.9
Florida	78.3	52.6
Georgia	95.9	47.4
Hawaii	98.1	49.5
Idaho	86.3	57.3
Illinois	104.2	58.1
Indiana	94.9	54.2
Iowa	64.5	60.1
Kansas	100.6	53.7
Kentucky	104.1	54.0
Louisiana	90.4	54.6
Maine	93.5	50.7
Maryland	78.5	50.5
Massachusetts	112.9	56.7
Michigan	107.1	57.9
Minnesota	97.8	52.7
Mississippi	99.2	53.0
Missouri	95.3	46.4
Montana	64.6	50.3
Nebraska	94.6	62.2
Nevada	88.2	53.4
New Hampshire	116.8	57.3
New Jersey	93.2	53.9
New Mexico	99.3	57.2
New York	86.8	48.7
North Carolina	97.5	58.6
North Dakota	97.5	59.6
Ohio	78.5	58.4
Oklahoma	97.0	56.5
Oregon	109.3	51.5

State[a]	Percentage of acquisition costs[b] that would have been covered by the AMP-based FUL, in the aggregate, for 83 drugs	Percent of Medicaid utilization represented by 83 drugs
Pennsylvania	89.7	56.4
South Carolina	85.6	56.7
South Dakota	106.7	61.9
Texas	92.4	66.4
Utah	82.7	59.9
Vermont	93.2	52.7
Virginia	87.0	57.8
Washington	117.6	49.1
West Virginia	79.6	56.3
Wisconsin	98.3	48.4
Wyoming	149.1	72.3

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

Notes:

[a]At the time we requested them from CMS, drug utilization data were not available for the second quarter of 2008 for Alabama, Arizona, Rhode Island, and Tennessee, and the U.S. territories of American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the Virgin Islands. Because we lacked utilization data for these states and territories, they have been excluded from our aggregate analyses.

[b]The average retail pharmacy acquisition cost data that we obtained from IMS Health do not account for rebates and discounts that pharmacies may receive from wholesalers or manufacturers, if they are not reflected in invoice prices. We were unable to identify any data sources of acquisition costs for multiple-source outpatient prescription drugs that account for rebates and discounts. We used national pharmacy acquisition costs to conduct this analysis because acquisition cost data were not available at the state level.

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

NOV 10 2009

John E. Dicken
Director, Health Care
U.S. Government Accountability Office
441 G Street N.W.
Washington, DC 20548

Dear Mr. Dicken:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: "Medicaid Outpatient Prescription Drugs: 2008 Federal Upper Limits for Reimbursement Compared with Average Retail Pharmacy Acquisition Costs" (GAO-10-118R).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

Andrea Palm
Acting Assistant Secretary for Legislation

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: NOV 10 2009

TO: Andrea Palm
Acting Assistant Secretary for Legislation
Office of the Secretary

FROM: Charlene Frizzera
Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Government Accountability Office (GAO) Draft Correspondence, "Medicaid Outpatient Prescription Drugs: 2008 Federal Upper Limits for Reimbursement Compared with Average Retail Pharmacy Acquisition Costs" (GAO-10-118R)

Thank you for the opportunity for the Centers for Medicare & Medicaid Services (CMS) to review and comment on the above-mentioned GAO draft report. The correspondence examines the relationship between the average manufacturer price (AMP) based Federal upper limit (FUL) reimbursement under the Deficit Reduction Act of 2005 (DRA) and what GAO terms the "average retail pharmacy acquisition costs" for selected drugs and provides additional information on how the AMP-based FULs would affect retail pharmacies.

We appreciate the time and effort that went into producing this study. However, we do not agree with the GAO's findings. We are concerned with the use of the undiscounted national average retail pharmacy acquisition cost data that GAO obtained from IMS Health that does not include discounts and rebates, as well as the methodology GAO used in its analyses.

The DRA intended to make accurate pricing data transparent to assure that the Federal government and State Medicaid programs are paying appropriately for drugs. We believe that as long as States must rely on drug prices that are not based on verifiable data, reimbursement to pharmacies will continue to be inflated and the cost to the Medicaid program will continue to escalate.

CMS Response

In general, the GAO study stated that the AMP-based FULs for the second quarter of 2008 would have been lower than the undiscounted average retail pharmacy acquisition cost for 54 of the 83 drugs in this study. Since the GAO did not release the data on which the study is based, we are concerned that GAO may have used incomplete and misleading information. In addition,

we have concerns with the comparison between data compiled by IMS Health and AMP. The "average retail pharmacy cost" data compiled by IMS Health does not account for rebates or discounts that pharmacies receive from manufacturers or wholesalers. Therefore, comparing undiscounted costs to AMP may not be useful. We believe that a more thorough analysis of the actual pharmacy acquisition costs is necessary.

Data Concerns

Our first significant concern is with GAO's use of the undiscounted average retail pharmacy acquisition cost data in this analysis. Undiscounted average retail pharmacy acquisition costs are not a good proxy for actual pharmacist acquisition costs because they do not reflect any of the rebates or discounts the pharmacies received when purchasing these drugs. Although GAO acknowledges the disadvantages of using an undiscounted average retail pharmacy acquisition cost, GAO does not account for this overstatement of pharmacy acquisition cost. Accordingly, we note that such a comparison to an AMP-based FUL is not a valid price comparison, as AMP is defined to include all discounts and rebates to the retail pharmacy class of trade. GAO's comparison would be synonymous with saying that current State payments for drugs are insufficient because they do not reflect the reported average wholesale price (AWP) of the drug, a pricing point known to be inflated and not related to actual pharmacy acquisition cost. We urge GAO to revise and republish this study using actual pharmacy acquisition costs to compare to the AMP-based FUL for these drugs.

We were unsuccessful in obtaining this data or an explanation of how IMS Health arrived at the undiscounted national average retail pharmacy acquisition cost used in this report. We were also unsuccessful in getting GAO to compare the undiscounted average acquisition cost to our current FULs based on published compendia prices. Nevertheless, we were able to perform an analysis based on the limited pricing information provided to CMS from GAO. Our analysis found that even the undiscounted average retail pharmacy acquisition cost was significantly below the AWP in almost all cases, and in some cases, equated to more than a 95 percent discount to the AWP. Therefore, if the actual pharmacy acquisition cost were used in GAO's analysis, we believe it would have shown prices that were even further discounted compared to the AWP.

Inconsistency with Office of Inspector General Findings

The Office of Inspector General (OIG) conducted a study of pharmacy acquisition costs and was able to include pharmacy discounts and rebates for half of the wholesaler/distributor respondents. Therefore, we believe that their findings offer a more accurate reflection of the market. Also, the OIG was able to analyze the lowest pharmacy acquisition cost. Inasmuch as CMS expects pharmacies to be prudent buyers and purchase the lowest cost drug rather than the drug with the highest spread between cost and payment, we also think that the OIG is a fairer comparison.

In the limited analysis we were able to do, we found the undiscounted average acquisition costs were significantly higher than the prices reported by OIG. We were able to match 27 drugs that are on both the OIG and the GAO sample drug lists. We found that for 19 of the 27 drugs, GAO's undiscounted average retail pharmacy acquisition costs were higher than OIG's average acquisition cost, ranging from at least 6 percent to 309 percent higher. While OIG's average acquisition cost data was from fourth quarter of 2007, CMS does not believe that a generic drug price would increase 309 percent over a two-quarter period. If anything, generic drug prices should decrease over time due to the increase in the number of generic products entering the market and competition among the generic manufacturers.

Additionally, CMS found that for one product, GAO's undiscounted average retail pharmacy acquisition cost was 44 percent lower than OIG's lowest acquisition cost reported. It seems unlikely that GAO's undiscounted average retail pharmacy acquisition cost should be lower than OIG's lowest acquisition cost reported. Because of the significant limitations we identified in GAO's undiscounted average retail pharmacy acquisition cost data, we strongly urge GAO to revise their study.

Methodology Concerns

The CMS also has concerns regarding the use of the median AMP-based FUL for this study. GAO simply used the middle AMP-based FUL value of three months. This is not an appropriate methodology to evaluate the adequacy of the monthly AMP-based FUL. If CMS was to provide States with the AMP-based FUL, it would be done monthly so that States could determine reimbursement monthly as well. Since each individual month's AMP-based FUL would be published and used as a reimbursement pricing point, using the median AMP-based FUL over a three-month period to compare to an undiscounted average retail pharmacy acquisition cost is not an accurate depiction of how States would have applied these FULs.

Further Limitations

The CMS has concerns that GAO's findings do not take into account the impact of the existing State cost-containment mechanisms such as the State Maximum Allowable Cost (MAC) programs. While this report notes that State Medicaid programs consider several methods for reimbursing pharmacies for multiple-source drugs and that Medicaid typically reimburses pharmacies at a rate lower than the published FUL, it fails to evaluate this effect on pharmacy reimbursement. The report should have also taken into consideration the current State MACs instead of the just the median AMP-based FULs.

This report only includes 83 drugs in its sample; therefore, it is not a true reflection of all drug groups subject to the AMP-based FUL. The average number of AMP-based FUL groups for the second quarter of 2008 was 1,315 groups, which means that the GAO report only reflects about

6.3 percent of the overall AMP-based FUL groups. We believe the inclusion of these other groups would have altered GAO's findings, noting that the FUL is calculated in the aggregate and is not based on an individual drug or on a sampling of drug groups.

Concluding Remarks

The CMS is aware that the AMP-based FULs fluctuate from month to month and we are considering measures to ensure that pharmacy reimbursement is fair and adequate and that all manufacturers report their data timely. We also note that we may need to otherwise account for these fluctuations. When we processed the FULs for each of the three months in the second quarter of 2008, we had monthly AMPs for approximately 81 percent of the National Drug Codes (NDC) in our system reported and certified by manufacturers. Since that time, we are seeing a significant increase in the percentage of timely reported and certified data. However, due to the preliminary injunction issued by the U.S. District Court for the District of Columbia on December 19, 2007, we are not able to implement the FULs provisions of the DRA. When we are able to implement AMP-based FULs, our goal is to have 100 percent of all the NDCs reported and certified before the FULs are processed. We also note that when we are able to publicly disclose the AMP data, this will help bring transparency to drug prices to ensure that pharmacies know which generic version of the drug can be purchased at less than the FUL amount.

We again thank GAO for the opportunity to review and comment on this draft correspondence.

Enclosure V

GAO Contact and Staff Acknowledgments

GAO Contact

John E. Dicken, (202) 512-7114 or DickenJ@gao.gov

Staff Acknowledgments

In addition to the contact named above, key contributors to this report were Will Simerl, Assistant Director; Rashmi Agarwal; Karen Howard; Julian Klazkin; Alexis MacDonald; Daniel Ries; Timothy Walker; and Michael Zose.

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