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United States Government Accountability Office
Washington, DC 20548

December 15, 2010

The Honorable Henry A. Waxman
Chairman
Committee on Energy and Commerce
House of Representatives

Subject: *Medicaid Outpatient Prescription Drugs: Estimated Changes to Federal Upper Limits Using the Formula under the Patient Protection and Affordable Care Act*

Dear Mr. Chairman:

Spending on prescription drugs in Medicaid—the joint federal-state program that finances medical services for certain low-income adults and children—totaled $15.2 billion in fiscal year 2008.[1] State Medicaid programs do not directly purchase prescription drugs; instead, they reimburse retail pharmacies for covered prescription drugs dispensed to Medicaid beneficiaries. The federal government provides matching funds to state Medicaid programs to help cover a portion of the cost of these reimbursements.[2]

For certain outpatient prescription drugs for which there are three or more therapeutically equivalent versions,[3] state Medicaid programs may only receive federal matching funds for reimbursements up to a maximum amount, which is known as a federal upper limit (FUL). FULs were designed as a cost-containment strategy and have historically been calculated as 150 percent of the lowest published price for the therapeutically equivalent versions of a given drug from among the prices published nationally in three drug pricing compendia. The prices from these compendia are list prices suggested by drug manufacturers and do not reflect actual transaction prices. State Medicaid programs have the authority to determine their own reimbursement amounts to retail pharmacies for covered prescription drugs. However, for drugs subject to a FUL, the federal government will only provide matching funds to the extent that a state's annual reimbursements do not exceed the sum of the FULs

[1]Medicaid spent $23.6 billion on prescription drugs in 2008, however this amount was offset by $8.4 billion in drug rebates paid by manufacturers to state Medicaid programs. Medicaid officials told us they could not report how much of this total Medicaid prescription drug spending was specifically for outpatient drugs.

[2]The portion of the cost paid by the federal government varies from state to state.

[3]Drugs determined by the Food and Drug Administration to be therapeutically equivalent can be substituted with the full expectation that they will produce the same clinical effect and safety profile as each other. They must contain the same active ingredient(s) and have the same dosage form, route of administration, and strength.

for all such drugs.[4] Concerns have been raised about FULs calculated based on compendia prices. For example, a 2005 report by the Department of Health and Human Services (HHS) Office of Inspector General (OIG) found that FULs calculated in this manner were ineffective at controlling spending on these drugs. The 2005 OIG report found that the prices in the three price compendia used to set FULs often greatly exceeded prices in the marketplace.

The Deficit Reduction Act of 2005 (DRA) established a FUL formula based on average manufacturer price (AMP) rather than compendia prices. In contrast to compendia prices, AMP represents the average of actual transaction prices paid to manufacturers for a given drug and is typically less than any of a drug's published compendium prices. Drug manufacturers are required to report AMPs to the Centers for Medicare and Medicaid Services (CMS) on a monthly basis. DRA also expanded the list of drugs subject to a FUL from those with three or more therapeutically equivalent versions to include drugs with two or more therapeutically equivalent versions.[5]

In 2006 and again in 2009, we compared FULs based on the DRA formula to average retail pharmacy acquisition costs, and reported that FULs based on the DRA formula, if implemented, would have been lower than retail pharmacy acquisition costs, on average, for the drugs in our samples.[6] In addition, retail pharmacies raised concerns that the formula in DRA for calculating FULs might not provide sufficient reimbursement to cover their costs for acquiring outpatient prescription drugs. As a result of litigation initiated by two retail pharmacy industry groups, the U.S. District Court for the District of Columbia issued a preliminary injunction in December 2007 that prohibited CMS from implementing the rule on AMP-based FULs promulgated under the DRA.[7]

Congressional interest in controlling prescription drug costs using AMP-based FULs continues. The Patient Protection and Affordable Care Act (PPACA) established a new AMP-

[4]For the group of drugs subject to FULs, the Centers for Medicare and Medicaid Services (CMS)—the agency within HHS that oversees Medicaid—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. Specifically, the FUL for each drug is multiplied by the number of units of each drug dispensed in a given state for a given year. The resulting dollar amounts are added across all drugs subject to a FUL and the sum total represents the maximum amount eligible for federal matching funds. Therefore, it might be possible for a state Medicaid program to reimburse pharmacies at an amount above the FUL for certain drugs if it also reimburses them at an amount below the FUL for other drugs.

[5]Pub. L. No. 109-171, § 6001(a)(2), 120 Stat. 4, 54-55 (2006).

[6]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 *Medicaid Outpatient Prescription Drugs: Second Quarter 2008 Federal Upper Limits for Reimbursement Compared with Average Retail Pharmacy Acquisition Costs*, GAO-10-118R (Washington, D.C.: Nov. 30, 2009).

[7]Subsequently, Congress passed the Medicare Improvements for Patients and Providers Act of 2008, which prohibited implementation prior to October 1, 2009. Pub. L. No. 110-275, § 203, 122 Stat. 2494, 2592. While the statutory prohibition has now expired, the preliminary injunction remains in place.

based formula for calculating FULs and changed the definition of AMP.[8] Under PPACA, FULs are to be calculated as no less than 175 percent of the utilization-weighted average of the most recently reported monthly AMPs for the pharmaceutically and therapeutically equivalent versions of a drug. You expressed interest in an early indication of the potential effects of PPACA on FULs and asked us to examine the likely effects of PPACA's AMP-based formula by drawing upon data from 2008 that we gathered for our November 2009 report, including 2008 AMPs that pre-date PPACA's changes to the definition of AMP. This report examines how, for selected drugs, estimated FULs using PPACA's AMP-based formula and 2008 data compare to pre-PPACA FULs and to average retail pharmacy acquisition costs.

Specifically, in order to compare FULs calculated using PPACA's formula, pre-PPACA (compendia-based) FULs that are currently in effect, and average pharmacy acquisition costs for selected drugs, we relied on a subset of the drugs selected for our November 2009 report on FULs. The sample in our 2009 report—in keeping with the expanded definition of drugs subject to a FUL under DRA—was drawn from all drugs with two or more therapeutically equivalent versions. This sample comprised the 50 drugs with the highest Medicaid volume and the 50 drugs with the highest Medicaid expenditures on a national level, based on Medicaid data for the second quarter of 2008.[9] Allowing for overlap between the two groups, a total of 83 drugs were in the sample used for our 2009 report. However, we did not use all of these drugs for our current review because PPACA struck the DRA provision that expanded the list of drugs subject to a FUL, thus applying FULs to drugs with three or more therapeutically equivalent versions and excluding drugs with only two therapeutically equivalent versions. This change narrowed the final sample for our current review to 40 of the 83 original drugs.[10] (See encl. I for a list of the 40 drugs in our sample.)

We produced estimates of the FULs for the 40 drugs in our sample using the formula specified in PPACA as well as AMP and utilization data from second quarter 2008. We used AMP data we obtained from CMS for our November 2009 report; that is, AMPs for each therapeutically equivalent version of each of the 40 drugs in our sample for April, May, and June of 2008.[11] As previously noted, these AMPs do not reflect PPACA provisions that changed the definition of AMP because PPACA-defined AMPs were not available at the time of our review. In October 2010, CMS officials told us they were not yet in the process of implementing PPACA's FUL provisions, and could not say when PPACA-defined AMPs would be available. In order to provide timely information on FULs under PPACA, we decided to use AMP data from the second quarter of 2008 rather than waiting for PPACA-defined AMPs. We calculated a median AMP for each of the 40 drugs in our sample for the second quarter of 2008. We did this by multiplying the monthly AMPs for each therapeutically equivalent

[8]Pub. L. No. 111-148, § 2503(a), 124 Stat. 119, 310-312 (2010), as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA), Pub. L. No. 111-152, § 1101(c), 124 Stat. 1029, 1039, and Pub. L. No. 111-226, § 202, 124 Stat. 2389, 2394 (2010). For purposes of this report, references to PPACA include the amendments made by HCERA and Public Law No. 111-226. PPACA changes the definition of AMP by excluding service fees paid by manufacturers, reimbursements made by manufacturers, and certain payments and discounts; specifying that AMPs will be based on drugs purchased by or for retail community pharmacies including independent or chain pharmacies, among others, and excluding, among others, mail-order and nursing home pharmacies. This change excludes from the calculation of AMP payments received from, and rebates or discounts provided to, hospitals, clinics, and mail-order pharmacies, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy.

[9]Dispensing fees were excluded when calculating Medicaid expenditures.

[10]Our subset of 40 drugs accounted for 48 percent of the total Medicaid utilization in that quarter for all such drugs and 36 percent of the total Medicaid expenditures for all such drugs.

[11]Manufacturers are required to report these data to CMS within 30 days of the end of every month.

version of a given drug by the drug's utilization to obtain a mean AMP for each drug in each of the 3 months. We then selected the median AMP for the quarter from among these three values in order to facilitate a comparison to pre-PPACA FULs and average retail pharmacy acquisition costs, both of which are calculated on a quarterly basis.[12] Finally, we multiplied the median AMP for each of the 40 drugs in our sample by 175 percent to estimate what the FULs for these drugs would be based on second quarter of 2008 AMP data and using PPACA's formula. In order to compare FULs using PPACA's formula to pre-PPACA FULs, we obtained the pre-PPACA FULs for each of the 40 drugs in our sample as of June 30, 2008—the end of the second quarter—from transmittal notices that are publicly available from CMS.

In order to compare FULs using PPACA's formula to pharmacy acquisition costs, we used national average retail pharmacy acquisition cost data from the second quarter of 2008. We obtained these data from IMS Health for our November 2009 report.[13] We used the IMS Health data to calculate a single pharmacy acquisition cost for each of the 40 drugs in our sample. This acquisition cost reflects the average cost of each drug's therapeutically equivalent versions, which we weighted to account for differences in their utilization. We then compared the FULs we estimated for each of the 40 drugs using PPACA's formula to the corresponding pharmacy acquisition cost. We also compared, in the aggregate, the sum of the FULs for all 40 drugs with the sum of their pharmacy acquisition costs in the second quarter of 2008.

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 August 2010 through October 2010, 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.

In summary, we found that for most of the drugs in our sample, using AMP and other data from 2008, FULs based on PPACA's formula were lower than pre-PPACA FULs and higher than average retail pharmacy acquisition costs. Specifically, the FULs based on PPACA's formula were lower than pre-PPACA FULs for 36 of the 40 drugs in our sample. For 34 out of the 40 drugs, the FULs based on PPACA's formula were higher than the drugs' pharmacy acquisition costs. In the aggregate, the sum of the FULs based on PPACA's formula for all the drugs in our sample was 35 percent higher than the sum total of the pharmacy acquisition

[12]We calculated the median FUL for the second calendar quarter of 2008 from the 3 months of FUL data provided by CMS in order to compare FULs based on PPACA's new formula to pre-PPACA FULs and average pharmacy acquisition costs, both of which were obtained on a quarterly basis.

[13]IMS Health obtains sales transaction data from about 100 drug manufacturers and about 500 distribution centers. 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. The national average pharmacy acquisition costs that we obtained from IMS Health may be greater than actual retail pharmacy acquisition costs because these data do not account for rebates that pharmacies may receive from wholesalers or manufacturers, if they were not reflected in invoice prices. 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, retail pharmacies can negotiate rebates on a manufacturer's entire line of products rather than per drug. Given the difficulty of identifying the dollar amount of rebates for specific versions of a drug and the lack of a comprehensive source of such data, we did not include rebates in our analysis.

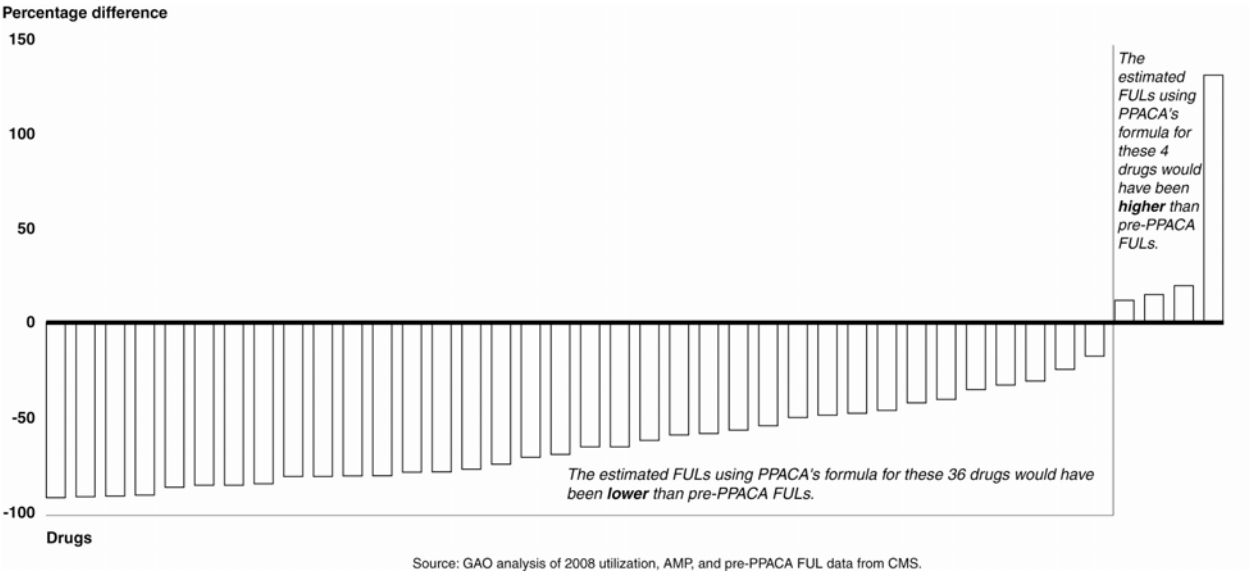
costs for these drugs. Thus, using PPACA's formula would have reduced Medicaid expenditures for the drugs in our sample by a significant amount compared to actual expenditures on these drugs in the second quarter of 2008, while still providing reimbursement that exceeded pharmacy acquisition costs. Furthermore, if PPACA-defined AMPs—which were not available at the time we conducted our study and which HHS officials told us are likely to be higher than pre-PPACA AMPs for the drugs in our sample—had been used with PPACA's formula, the FULs we estimated likely would have been higher for our sample of drugs. This would have reduced the difference between the FULs based on PPACA's formula and the pre-PPACA FULs, thus reducing the estimated savings attributed to PPACA-defined FULs. In addition, using PPACA-defined AMPs would likely have increased the amount by which FULs would have exceeded average retail pharmacy acquisition costs.

In its written comments on a draft of this report, HHS neither agreed nor disagreed with our finding that FULs using PPACA's formula would have substantially exceeded pharmacy acquisition costs in the second quarter of 2008. HHS reiterated the data limitations we noted in the draft report; namely, that the retail pharmacy acquisition costs we used did not include rebates that pharmacies may receive from wholesalers or manufacturers and that the AMPs we used do not reflect PPACA's revisions to the calculation of AMPs. As we noted, rebate data and PPACA-defined AMPs were not available and, in both cases, would likely cause FULs to exceed pharmacy acquisition costs to an even greater degree than we estimated.

FULs Based on PPACA's Formula Were Lower Than Pre-PPACA FULs, but Still Significantly Higher Than Average Retail Pharmacy Acquisition Costs

Using AMP and other data from 2008, we found that FULs estimated using PPACA's formula were lower than pre-PPACA FULs for 36 of the 40 drugs in our sample. (See fig. 1.) In the aggregate, the sum total of the FULs using PPACA's formula for all the drugs in our sample was 78 percent lower than the sum total of the pre-PPACA FULs for the sample.

Figure 1: Percentage That Estimated FULs Based on the PPACA Formula and 2008 Data Are Lower or Higher Than Pre-PPACA FULs, Second Quarter 2008



Source: GAO analysis of 2008 utilization, AMP, and pre-PPACA FUL data from CMS.

Note: AMP data obtained from CMS do not include changes in the calculation of AMPs by manufacturers as mandated by PPACA. These data were not available at the time of our analysis.

Furthermore, if FULs estimated using PPACA's formula had been in place in the second quarter of 2008, they would have reduced Medicaid expenditures for the drugs in our sample by a significant amount. Specifically, FULs estimated using PPACA's formula for the 40 drugs in our sample during the second quarter of 2008 were more than 60 percent lower than actual expenditures on these drugs during the same time period. Excluding dispensing fees paid to pharmacies, actual Medicaid expenditures for the 40 drugs in our sample totaled about $109 million for the second quarter of 2008, while expenditures would have totaled about $42 million if limited by FULs using PPACA's formula.

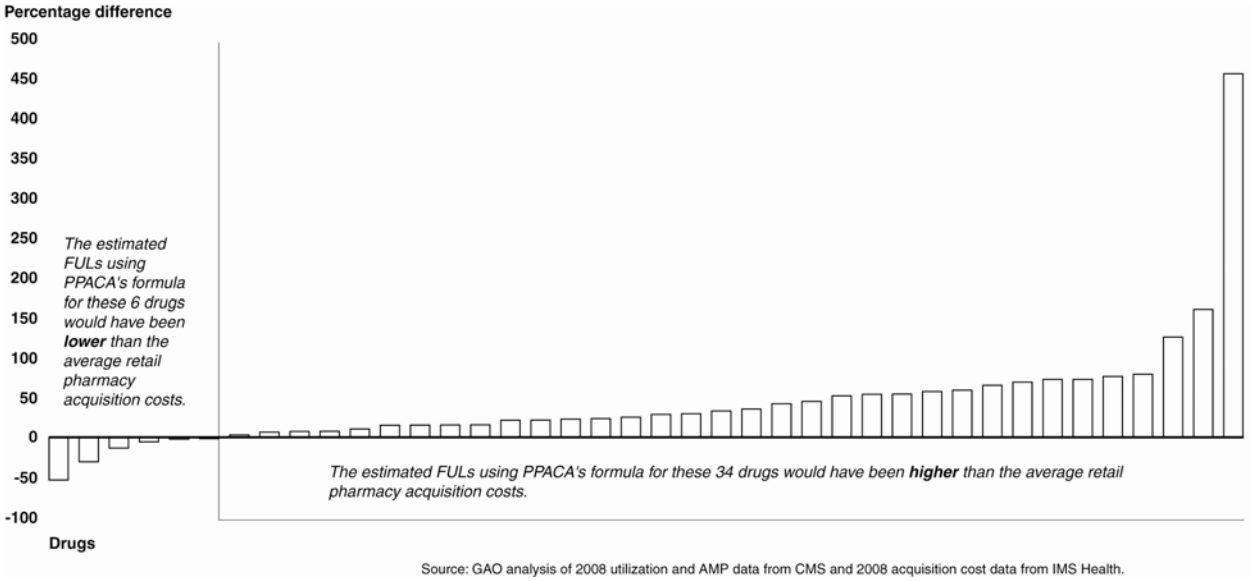
FULs calculated using PPACA's formula and PPACA-defined AMPs—which were not available at the time we conducted our study and which HHS officials told us are likely to be higher than pre-PPACA AMPs for the drugs in our sample—would likely have been higher than the FULs we estimated. This would have narrowed the difference between FULs based on PPACA's formula and pre-PPACA FULs and reduced the estimated savings that could be obtained using PPACA-defined FULs.[14]

Although FULs estimated using PPACA's formula and AMP and other data from 2008 were substantially lower than pre-PPACA FULs for most of the drugs in our sample, we also found that for most of these drugs, the estimated FULs were still significantly higher than average retail pharmacy acquisition costs. Specifically, FULs based on PPACA's formula and 2008 data were higher than pharmacy acquisition costs for 34 out of the 40 individual drugs in our sample. (See fig. 2.) For the majority of the drugs, the estimated FULs were at least 20 percent higher than the pharmacy acquisition cost. In the aggregate, the sum total of FULs based on PPACA's formula and 2008 data for our sample of drugs was still 35 percent higher than the sum of the drugs' pharmacy acquisition costs.[15]

[14]Unlike DRA, which made drugs with two or more therapeutically equivalent versions subject to FULs, PPACA applies FULs only to drugs with three or more therapeutically equivalent versions. With this change, significantly fewer drugs will be subject to FULs. Based on the data we gathered for our 2009 report and excluding dispensing fees, we estimate that 590 drugs representing about $340 million in expenditures would have been subject to a FUL under PPACA's definition during the second quarter of 2008. In contrast, an additional 804 drugs representing $604 million more in expenditures would have been subject to a FUL if DRA's definition had been in place during the second quarter of 2008.

[15]By comparison, in our November 2009 report we found that FULs based on DRA's formula for the second quarter of 2008, in the aggregate across the larger sample of 83 drugs examined in that report, would have been 17 percent lower than average retail pharmacy acquisition costs for the same period.

Figure 2: Percentage That Estimated FULs Based on the PPACA Formula and 2008 Data Are Higher or Lower Than Average Retail Pharmacy Acquisition Costs, Second Quarter 2008



Note: AMP data obtained from CMS do not include changes in the calculation of AMPs by manufacturers as mandated by PPACA. These data were not available at the time of our analysis.

It is important to note that the actual relationship between the FULs and acquisition costs will be affected by several additional factors. For example, the acquisition cost data we used generally do not include rebates paid by manufacturers to retail pharmacies. If included, any applicable rebates would have reduced the average retail acquisition costs for the drugs in our sample. Therefore, FULs using the PPACA formula would have exceeded retail pharmacy acquisition costs to an even greater degree than the 35 percent we estimated. Similarly, FULs calculated using PPACA-defined AMPs—which were not available at the time we conducted our study and which HHS officials told us are likely to be higher than pre-PPACA AMPs for the drugs in our sample—would likely have been higher than the FULs we estimated, causing them to exceed retail pharmacy acquisition costs to an even greater degree than our estimate of 35 percent.

Agency Comments and Our Evaluation

HHS provided written comments on a draft of this report, which are reprinted in enclosure II. HHS neither agreed nor disagreed with our finding that FULs using PPACA's formula would have substantially exceeded pharmacy acquisition costs in the second quarter of 2008. In its comments, HHS reiterated a limitation that we explained in our draft report; namely, that the pharmacy acquisition cost data from IMS Health that we used did not include rebates paid by wholesalers and manufacturers to retail pharmacies. As we noted in the draft report, the IMS Health data we used may be greater than actual retail pharmacy acquisition costs because they do not account for rebates that pharmacies may receive from wholesalers or manufacturers, if they were not reflected in invoice prices. 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, retail pharmacies can negotiate rebates on a manufacturer's entire line of products rather than per drug. Given the difficulty of identifying the dollar amount of rebates for specific versions of a drug and the lack of a comprehensive source of such data, we did not include rebates in our analysis. However, we did note in the draft report that, if included, any applicable rebates would have reduced the average retail acquisition costs for the drugs in our sample. Therefore, FULs using the PPACA

formula would have exceeded retail pharmacy acquisition costs to an even greater degree than the 35 percent we estimated.

HHS also stated that our use of AMP data from 2008 does not reflect PPACA's revisions to the calculation of AMPs and that it would therefore be inappropriate to conclude that for a number of drugs, the PPACA-defined FULs would be lower than pharmacy acquisition costs. In other words, HHS questioned whether including PPACA's revisions would have shown that FULs estimated using PPACA's formula were higher than retail pharmacy acquisition costs for all 40 of the drugs in our sample, rather than for 34 of the 40 drugs, as we found. However, as we stated in the draft report, new AMP data that reflect PPACA's revisions were not available at the time of our analysis because CMS was not yet in the process of implementing PPACA's provisions related to FULs. While we have no way of determining the likely effect of PPACA's revisions on individual drugs in our sample, we noted in the draft report that PPACA-defined AMPs, according to HHS officials, are expected to be higher than the 2008 AMPs used for our analysis. We also noted in our draft report that these higher PPACA-defined AMPs would likely cause FULs to exceed pharmacy acquisition costs by an even greater degree than the 35 percent our findings indicate.

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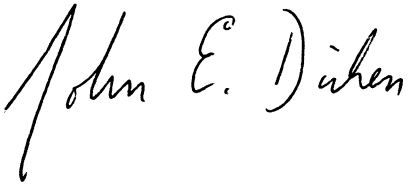
As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days after its issue date. At that time, we will send copies to the Secretary of Health and Human Services and interested congressional committees. The report will also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

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 III.

Sincerely yours,



John E. Dicken
Director, Health Care

Enclosures – 3

The 40 Medicaid Prescription Drugs GAO Reviewed and Sample Category into Which Each Drug Falls, 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)
Acetaminophen Hydrocodone Bitartrate 500mg/15ml; 7.5mg/15ml	Solution	High Utilization
Acetaminophen Hydrocodone Bitartrate 500mg; 10mg	Tablet	High Utilization and High Expenditure
Acetaminophen; Hydrocodone Bitartrate 500mg; 5mg	Tablet	High Utilization
Acetaminophen Oxycodone Hydrochloride 325mg; 5mg	Tablet	High Utilization
Alprazolam 0.25mg	Tablet	High Utilization
Alprazolam 0.5mg	Tablet	High Utilization
Alprazolam 1mg	Tablet	High Utilization
Amoxicillin 125mg/5ml	Suspension	High Utilization
Amoxicillin 250mg/5ml	Suspension	High Utilization
Amoxicillin Clavulanic Acid 400mg/5ml; 57mg/5ml	Suspension	High Utilization and High Expenditure
Chlorhexidine Gluconate 0.12%	Solution	High Utilization
Clonazepam 0.5mg	Tablet	High Utilization
Clonazepam 1mg	Tablet	High Utilization and High Expenditure
Clonidine Hydrochloride 0.1mg	Tablet	High Utilization
Cyclobenzaprine Hydrochloride 10mg	Tablet	High Utilization
Diazepam 10mg	Tablet	High Utilization
Diphenhydramine Hydrochloride 12.5mg/5ml	Elixir	High Utilization
Fluoxetine Hydrochloride 20mg	Capsule	High Utilization
Folic Acid 1mg	Tablet	High Utilization
Gabapentin 300mg	Capsule	High Utilization and High Expenditure
Gabapentin 600mg	Tablet	High Expenditure
Gabapentin 800mg	Tablet	High Expenditure

Drug name and strength	Dosage form	Sample category into which each drug falls (High Utilization, High Expenditure, or High Utilization and High Expenditure)
Hydrochlorothiazide 25mg	Tablet	High Utilization
Ibuprofen 600mg	Tablet	High Utilization
Ibuprofen 800mg	Tablet	High Utilization
Lactulose 10gm/15ml	Solution	High Utilization
Lorazepam 0.5mg	Tablet	High Utilization
Lorazepam 1mg	Tablet	High Utilization and High Expenditure
Metformin Hydrochloride 500mg	Tablet	High Utilization and High Expenditure
Metoclopramide Hydrochloride 5mg/5ml	Solution	High Utilization
Mupirocin 2%	Ointment	High Expenditure
Ofloxacin 0.3%	Solution/drops (Ophthalmic)	High Expenditure
Ofloxacin 0.3%	Solution/drops (Otic)	High Expenditure
Omeprazole 20mg	Delayed release capsule	High Expenditure
Paroxetine Hydrochloride 20mg	Tablet	High Expenditure
Ranitidine Hydrochloride 150mg	Tablet	High Utilization
Ribavirin 200mg	Capsule	High Expenditure
Tramadol Hydrochloride 50mg	Tablet	High Utilization and High Expenditure
Triamcinolone Acetonide 0.1%	Cream	High Utilization
Valproic Acid 250mg/5ml	Syrup	High Utilization

Source: GAO analysis of 2008 utilization and expenditure data from CMS.

Note: Dispensing fees were excluded when calculating Medicaid expenditures.

Enclosure II

Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

NOV 29 2010

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

Dear Mr. Dicken:

Attached are comments on the U.S. Government Accountability Office's (GAO) correspondence entitled: "Medicaid Outpatient Prescription Drugs: Estimated Changes to Federal Upper Limits Using the New Formula under the Patient Protection and Affordable Care Act"(GAO 11-141R).

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

Sincerely,

Jim R. Esquea

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT CORRESPONDENCE ENTITLED, "MEDICAID OUTPATIENT PRESCRIPTION DRUGS: ESTIMATED CHANGES TO FEDERAL UPPER LIMITS USING THE NEW FORMULA UNDER THE PATIENT PROTECTION AND AFFORDABLE CARE ACT" (GAO-11-141R)

The Department appreciates the opportunity to review and comment on this draft correspondence.

We note GAO's findings that the estimated FULs using the Affordable Care Act formula substantially exceed pharmacy acquisition costs to purchase these drugs. However, we continue to remain concerned that this correspondence overstates pharmacy acquisition costs by using fundamentally flawed data, as we noted in our disagreement with GAO's earlier reports on FULs, published in 2006 (GAO-07-239R) and in 2009 (GAO-10-118R). As GAO observed in this correspondence, the acquisition cost data used did not include rebates paid by wholesalers and manufacturers to retail pharmacies. If included, any applicable rebates would have reduced the average retail acquisition costs for the drugs in the sample, and the estimated FULs using the Affordable Care Act formula would have further exceeded the retail pharmacy acquisition costs.

Additionally, GAO used average manufacturer price (AMP) data from 2008 to estimate FULs using the Affordable Care Act formula. However, the Affordable Care Act fundamentally revised the calculation of AMP. The new AMPs, which are expected to be based on higher priced sales, are likely to be higher than the AMPs used in this correspondence. Therefore, we believe that there is little support for GAO's conclusion that for a number of drugs, the new Affordable Care Act FUL amounts would be lower than pharmacy acquisition costs.

We appreciate the efforts that went into this correspondence and look forward to working with GAO on this and other issues.

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; Zhi Boon; Krister Friday; Karen Howard; Julian Klazkin; and Carla Willis.

(290884)