Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

ANALYZING CHANGES TO MEDICAID FEDERAL UPPER LIMIT AMOUNTS

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Inspector General

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EXECUTIVE SUMMARY: ANALYZING CHANGES TO MEDICAID FEDERAL UPPER LIMIT AMOUNTS
OEI-03-11-00650

WHY WE DID THIS STUDY

Prior Office of Inspector General (OIG) work consistently found that the published prices used to set Medicaid's Federal upper limit (FUL) amounts often greatly exceeded prices available in the marketplace. Partly because of OIG work, provisions of the Deficit Reduction Act of 2005, P.L. 109-171, were crafted to substantially change the method for calculating FULs and most likely would have resulted in lower FUL amounts; however, these changes were never implemented because of an injunction against the Centers for Medicare & Medicaid Services (CMS) and subsequent changes in the law. The Affordable Care Act (ACA), P.L. 111-148, enacted in March 2010, also includes provisions that seek to change FUL amounts. In September 2011, CMS began releasing the new FUL amounts to the public in draft form. Given our previous findings that FUL amounts based on published prices greatly exceeded pharmacy acquisition costs and that the new FUL amounts have not taken effect, we compared FUL amounts based on published prices to FUL amounts based on average manufacturer prices (AMP) and then compared both FUL amounts to pharmacy acquisition costs.

HOW WE DID THIS STUDY

We compared aggregate pharmacy acquisition costs for selected drugs to (1) FUL amounts based on published prices and (2) FUL amounts based on post-ACA AMPs. We also compared FUL amounts based on published prices to FUL amounts based on post-ACA AMPs and calculated the difference for each drug.

WHAT WE FOUND

We found that FUL amounts based on published prices were more than four times greater than sampled pharmacy acquisition costs. We also found that FUL amounts based on AMPs were 61 percent lower than FUL amounts based on published prices, at the median. Despite the reduction in proposed reimbursement, FUL amounts based on AMPs still exceed sampled pharmacy acquisition costs by 43 percent in the aggregate. CMS had not implemented FUL amounts based on AMPs as of August 2012. Although CMS has taken steps to implement FUL amounts based on AMPs by calculating the new amounts and issuing draft files for review, FUL amounts continued to be based on published prices as of August 2012.

WHAT WE RECOMMEND

Given the results of the body of OIG work and the potential reduction in Medicaid expenditures, we recommend that CMS complete the implementation of the post-ACA AMP-based FUL amounts. CMS concurred with our recommendation and stated that it plans to implement FUL amounts based on AMPs in the near future.

TABLE OF CONTENTS

OBJECTIVES

1. To compare pharmacy acquisition costs for selected drugs to Federal upper limit (FUL) amounts based on published prices.
2. To determine how FUL amounts would change under the average manufacturer price (AMP)-based methodology required by the Affordable Care Act (ACA), P.L. 111-148.
3. To compare pharmacy acquisition costs for selected drugs to FUL amounts based on AMPs.
4. To assess the Centers for Medicare & Medicaid Services' (CMS) implementation of FUL amounts based on AMPs.

BACKGROUND

The FUL program was established to ensure that Medicaid takes advantage of lower market prices for multiple-source drugs.[1] Prior Office of Inspector General (OIG) work consistently found that the published prices used to set FUL amounts often greatly exceeded prices available in the marketplace. Partly because of OIG work, provisions of the Deficit Reduction Act of 2005 (DRA), P.L. 109-171, were crafted to substantially change the method for calculating FULs and most likely would have resulted in lower FUL amounts; however, these changes were never implemented because of an injunction against CMS and subsequent changes in the law. The ACA, enacted in March 2010, includes provisions that seek to change FUL amounts. In September 2011, CMS began releasing files containing draft FUL amounts based on the new methodology required by the ACA.

Medicaid Reimbursement for Prescription Drugs

Medicaid, established under Title XIX of the Social Security Act (the Act), is administered by States and financed using State and Federal funds. All 50 States and the District of Columbia (hereinafter referred to as States) offer prescription drug coverage as part of their Medicaid benefit packages. Medicaid expenditures for prescription drugs totaled approximately $29 billion in 2010.[2]

Medicaid beneficiaries typically receive covered drugs through pharmacies, which are reimbursed by State Medicaid agencies. Federal regulations require, with certain exceptions, that each State Medicaid

[1] Generally, a drug is considered multiple-source if generic versions are available.

[2] Medicaid expenditures were calculated using data from CMS's Medicaid Budget and Expenditure System. This total does not reflect rebates collected through the Medicaid drug rebate program.

agency's reimbursement for a covered outpatient drug not exceed (in the aggregate) the lower of (1) the estimated acquisition cost plus a reasonable dispensing fee or (2) the provider's usual and customary charge to the public for the drug.[3] CMS allows States flexibility to define estimated acquisition cost; most States base their calculations on average wholesale prices (AWP) or wholesale acquisition costs (WAC).[4, 5]

CMS is collecting national average drug acquisition cost data to develop a new reimbursement benchmark for State Medicaid agencies that is more reflective of pharmacies' acquisition costs. To develop this benchmark, CMS will obtain actual pharmacy drug acquisition costs from a random sample of pharmacies using a monthly nationwide survey.

Medicaid FUL Program

To reduce expenditures for Medicaid prescription drugs, CMS and the States have implemented certain cost containment measures, including the FUL program.[6] The FUL program limits Medicaid reimbursement for certain multiple-source drugs and seeks to ensure that the Federal Government acts as a prudent buyer by taking advantage of market prices for these drugs. CMS calculates a FUL amount for specific forms and strengths for each multiple-source drug that meets the established criteria.[7, 8] According to CMS data, FUL drugs accounted for $2.4 billion in Medicaid expenditures in 2010.[9]

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[3] 42 CFR § 447.512. CMS issued a proposed rule in February 2012 that would replace estimated acquisition cost with actual acquisition cost as the basis of Medicaid pharmacy reimbursement. In the proposed rule, CMS states that the data used to calculate actual acquisition costs will be more reflective of pharmacies' purchase prices. See 77 Fed. Reg. 5318, 5320–5321 (Feb. 2, 2012).

[4] The majority of States obtained AWPs from the publisher First DataBank. However, First DataBank stopped publishing AWPs as of September 2011. This has forced many States to reevaluate their reimbursement methodologies. See OIG, *Replacing Average Wholesale Price: Medicaid Drug Payment Policy* (OEI-03-11-00060), July 2011.

[5] CMS, *Medicaid Prescription Reimbursement Information by State – Quarter Ending December 2011*. Accessed at http://www.cms.hhs.gov on February 17, 2012.

[6] Other examples of cost containment measures include State maximum allowable cost (MAC) programs and the Medicaid drug rebate program.

[7] CMS, *Transmittal No. 37 – Federal Upper Limit Drug List*. Accessed at http://www.cms.hhs.gov on July 15, 2011.

[8] Section 1927(e)(4) of the Act generally requires CMS to establish a FUL amount when three or more formulations of the drug were rated as therapeutically and pharmaceutically equivalent by the Food and Drug Administration. Additional requirements as set forth in 42 CFR § 447.332 include that at least three suppliers of the drug are listed in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

[9] Medicaid expenditures were calculated from CMS's 2010 Medicaid Drug Rebate Program Utilization Data. This total does not include rebates.

Calculating FUL Amounts

Historically, CMS set FUL amounts equal to 150 percent of the price published in national compendia for the least costly therapeutically equivalent product that could be purchased by pharmacists in quantities of 100 tablets or capsules, plus a reasonable dispensing fee. (If the drug is not commonly available in quantities of 100, the package size commonly listed is used; in the case of liquids, the commonly listed size is used.)[10]

The most commonly used published prices in setting FULs are WACs, AWPs, and direct prices.[11] National compendia, such as *Redbook*, publish these figures based on information provided by drug manufacturers. Previous OIG work consistently found that the published prices used to set Medicaid FUL amounts often greatly exceeded prices available in the marketplace.[12]

Proposed Changes to FUL Amounts Under the DRA. Partly because OIG work showed that FUL amounts based on published prices were significantly higher than AMPs, the DRA proposed significant changes to the FUL program.[13] Section 6001(a) of the DRA changed the basis of FUL amounts from 150 percent of the lowest price published in national compendia to 250 percent of the lowest reported AMP.[14]

In July 2007, CMS promulgated a final rule that implemented the DRA provisions related to FULs.[15] The final regulation took effect on October 1, 2007, and CMS planned to issue the first AMP-based FULs on December 30, 2007. However, two trade associations representing retail pharmacies filed a lawsuit because they were concerned that the proposed FUL amounts calculated using the DRA method might not adequately reimburse providers for their costs, thereby limiting access to certain

[10] See, for example, 42 CFR § 447.332. This regulation has been removed. However, as of May 2012, CMS continues to use the FUL criteria found in 42 CFR § 447.332.

[11] Although the definition of WAC is prescribed by Federal law (at 42 U.S.C. § 1395w-3a (c)(6)), neither AWP nor direct price is defined in statute or regulation.

[12] For example, see OIG, *A Comparison of Medicaid Federal Upper Limit Amounts to Acquisition Costs, Medicare Payment Amounts, and Retail Prices* (OEI-03-08-00490), August 2009.

[13] OIG, *Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices* (OEI-03-05-00110), June 2005.

[14] Before October 2010, the AMP was generally defined by statute (at 42 U.S.C. § 1396r-8(k)(1)) to be the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. Pursuant to § 1927 (b)(3) of the Act, for Federal payment to be available for their covered outpatient drugs under Medicaid, manufacturers must provide AMPs to CMS monthly and quarterly.

[15] 72 Fed. Reg. 39142, 39244 (July 17, 2007). 42 CFR § 447.504 of the 2007 regulation outlined the manner in which the AMP is to be determined, and 42 CFR § 447.514 addressed the new criteria for the establishment of FUL amounts.

drugs.[16] In December 2007, a Federal judge issued a preliminary injunction preventing CMS from implementing the DRA-mandated AMP-based FUL amounts. In July 2008, the Medicare Improvements for Patients and Providers Act (MIPPA), P.L. 110-275, further delayed implementation of the DRA-mandated AMP-based FUL amounts.[17]

CMS formally withdrew the regulations implementing the DRA-based changes to FULs, effective December 2010, and the injunction against CMS was lifted in the same month.[18]

Proposed Changes to FUL Amounts Under the ACA. Section 2503 of the ACA amended section 1927(e) of the Act by revising FUL amounts to be no less than 175 percent of the weighted average of the most recently reported monthly AMPs.[19] This section of the ACA also amended section 1927(k) of the Act by revising the definition of AMP.[20, 21]

As of August 2012, CMS has continued to base FUL amounts on 150 percent of the lowest published price.[22] However, CMS has issued draft FUL amounts based on AMPs for review and comment.[23] Table 1 summarizes the proposed and actual methodology for calculating FUL amounts.

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[16] National Association of Chain Drug Stores (NACDS) and National Community Pharmacists Association (NCPA), *Frequently Asked Questions (FAQs) Lawsuit Filed by NACDS and NCPA Against CMS Challenging AMP Rule.* November 7, 2007. Accessed online at http://www.ncpanet.org on December 2, 2011.

[17] Consistent with §§ 203(a) and (b) of the MIPPA, CMS could not implement AMP-based FUL amounts or publicly disclose AMP data before October 2009.

[18] See 75 Fed. Reg. 69591, 69597 (Nov. 15, 2010). See *National Association of Chain Drug Stores, et al., v. U.S. Department of Health and Human Services, et al.*, Civil Action No. 1:07cv02017, order dated December 15, 2010.

[19] Changes to the FUL amount in the ACA superseded the DRA changes.

[20] Under the ACA provisions, the new definition of AMP is the average price paid to the manufacturer for the drug in the United States by (1) wholesalers for drugs distributed to retail community pharmacies and (2) retail community pharmacies that purchase drugs directly from the manufacturer.

[21] Pursuant to § 1927(k)(10) of the Act, "retail community pharmacy" means an independent, chain, supermarket, or mass-merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail; nursing home, long-term care, or hospital pharmacies; clinics; charitable or not-for-profit pharmacies; government pharmacies; or pharmacy benefit managers.

[22] CMS has calculated FUL amounts based on the requirements set forth in ACA, although it has not yet implemented them.

[23] CMS, *Draft Affordable Care Act Federal Upper Limit.* Accessed at http://www.cms.gov on February 9, 2012.

Table 1: Methodology for Calculating FUL Amounts

Timeframe	Statutory Methodology	Methodology Used
Pre-DRA (before October 1, 2007)	150% of the lowest published price	150% of the lowest published price
Post-DRA, Pre-ACA (October 1, 2007–September 30, 2010)	250% of the lowest AMP	150% of the lowest published price (changes not implemented because of injunction and MIPPA)
Post-ACA (October 1, 2010–August 2012)	No less than 175% of the weighted average AMP	150% of the lowest published price (interim methodology)

Source: OIG analysis of CMS FUL methodology, 2012.

Previous OIG and Government Accountability Office Work

An August 2009 OIG report found that FUL amounts based on published prices were substantially higher than acquisition costs, Medicare payment amounts, and retail prices, causing Medicaid to overpay hundreds of millions of dollars per year. OIG recommended that CMS continue to work with Congress to identify strategies that would lower inflated Medicaid payments for multiple-source drugs.[24] CMS concurred with this recommendation.

A September 2010 OIG report found that the majority of drug manufacturers did not comply with CMS's requirements for reporting monthly AMP data (i.e., the basis for FUL amounts required by the ACA). Because AMP data play a critical role in Medicaid payments for prescription drugs, OIG recommended that CMS take action against manufacturers that do not comply with AMP data submission requirements.[25] CMS concurred with this recommendation. In accordance with an enforcement initiative announced in September 2010, OIG has begun imposing civil money penalties (CMP) on certain manufacturers that fail to report timely AMPs.

A December 2010 Government Accountability Office (GAO) report found that FUL amounts based on AMPs were lower than FUL amounts based on published prices (i.e., pre-ACA FUL amounts) but still significantly higher than average retail pharmacy acquisition costs.[26] However, that study did not incorporate the new definition of AMP, and the retail pharmacy acquisition costs did not include rebates that pharmacies may receive from wholesalers or manufacturers.

[24] OIG, *A Comparison of Medicaid Federal Upper Limit Amounts to Acquisition Costs, Medicare Payment Amounts, and Retail Prices* (OEI-03-08-00490), August 2009.
[25] OIG, *Drug Manufacturers' Noncompliance With Average Manufacturer Price Reporting Requirements* (OEI-03-09-00060), September 2010.
[26] GAO, *Medicaid Outpatient Prescription Drugs: Estimated Changes to Federal Upper Limits Using the Formula under the Patient Protection and Affordable Care Act* (GAO-11-141R), December 2010.

METHODOLOGY

Data Sources and Collection

FULs. We obtained the November 2010, July 2011, and September 2011 draft files from CMS containing FUL amounts based on AMPs (i.e., the FUL amounts that would have been in effect had the ACA methodology been implemented).[27] We also obtained first- and fourth-quarter 2011 *Redbook* files containing FUL amounts based on published prices (i.e., the FUL amounts in effect). We also obtained CMS's policies and procedures regarding the FUL program.

Medicaid Utilization Data. We obtained a file from CMS containing 2010 State Medicaid expenditure (ingredient costs and dispensing fees), payment, and utilization data.[28]

Pharmacy Acquisition Cost. We collected drug acquisition cost data from a stratified random sample of pharmacies.[29] To obtain these data, we sent letters to 120 pharmacies in January 2011. We asked each pharmacy to provide drug acquisition costs by submitting its largest invoice for November 2010 from each source of supply.[30] Sources of supply include wholesalers, chain warehouse distribution centers, and generic distributors; and we also obtained data for direct manufacturer purchases. We received data from 117 of the 120 sampled pharmacies. We asked pharmacies to report any discounts applicable to the invoices provided. See the Appendix for a detailed description of the sampling design.

Data Analysis

We reviewed all of CMS's policies and procedures regarding the FUL program. We compared aggregate pharmacy acquisition costs in November 2010 to aggregate FUL amounts based on published prices (i.e., pre-ACA FUL amounts that were in effect as reported in the first-quarter 2011 *Redbook* file) and FUL amounts based on AMPs (i.e., post-ACA AMP-based FUL amounts as reported in the November 2010 draft CMS file). First, we identified all drugs associated with FUL amounts purchased by sampled pharmacies and totaled the pharmacy acquisition costs for these drugs. Then we estimated how much pharmacies would have been reimbursed by Medicaid for these drugs by

[27] CMS publicly released the first draft FUL amounts based on AMPs in September 2011; however, the agency internally calculated draft FUL amounts based on AMPs starting in November 2010.

[28] This file included data from 48 States. Three States (Alabama, Nevada, and Rhode Island) were not included in CMS's data at the time we obtained the file.

[29] The Office of Audit Services collected drug acquisition cost data from the sampled pharmacies. See *Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices* (A-06-11-00002), October 2011.

[30] We defined largest invoice as that with the largest number of legend drug line items.

multiplying the number of units purchased by FUL amounts based on published prices, as well as by FUL amounts based on AMPs, and totaled these respective amounts.[31] Finally, we compared actual pharmacy acquisition costs to estimated reimbursement amounts under both methodologies.

To determine how FULs would change under the ACA, we compared FUL amounts based on published prices from the fourth-quarter 2011 *Redbook* file to FUL amounts based on AMPs from the September 2011 draft CMS file and calculated the difference for each drug. We determined the number of drugs for which the FUL amount was higher and the number of drugs for which the FUL amount was lower under the new methodology. We also calculated the median percentage difference between the FUL amounts.

Further, we estimated how much Medicaid expenditures would have been reduced in November 2010 if reimbursement had been based on the draft FUL amounts from that month. State Medicaid expenditure data include dispensing fees; therefore, we calculated expenditures for the ingredient cost portion only.[32, 33] Because Medicaid utilization data are reported quarterly, we first calculated the quarterly expenditures for ingredient cost only and then divided by three to determine monthly expenditures.[34] We multiplied FUL amounts based on AMPs by the drug's fourth quarter-2010 utilization, summed the total, divided by three, and compared the estimate to actual November 2010 Medicaid expenditures based on ingredient cost only.

Finally, we examined CMS's ability to calculate FUL amounts based on AMPs by determining the availability of manufacturer-reported pricing data. See Table 2 for a description of the number of drugs included in each portion of our analysis.

[31] These totals do not include dispensing fees.

[32] In addition to the three States without any 2010 data, four other States did not have any utilization data for the fourth quarter of 2010 and were excluded from this analysis.

[33] We could only calculate ingredient costs for States that had relatively simple formulas for determining dispensing fees paid to pharmacies (e.g., $5 for generic drugs). Thirty-six of the 44 States included in this analysis had a relatively simple dispensing fee formula; we excluded the remaining 8 States from this portion of the analysis. For the 36 States, we calculated the total Medicaid ingredient cost for FUL drugs by subtracting the total dispensing fees paid from total expenditures in the fourth quarter of 2010. To calculate dispensing fees, we multiplied the State's dispensing fee from the fourth quarter of 2010 by the total number of prescriptions for each FUL drug.

[34] This calculation assumes utilization was consistent from 1 month to the next.

Table 2: Number of Drugs Included in Analysis

Analysis	Number of Drugs
Comparison of pharmacy acquisition costs to FUL amounts based on published prices	601
Comparison of FUL amounts based on published prices to FUL amounts based on AMPs	518
Comparison of actual Medicaid expenditures to estimated Medicaid expenditures had post-ACA AMPs served as the basis for FUL amounts (ingredient cost only)	416
Comparison of pharmacy acquisition costs to FUL amounts based on AMPs	328

Source: OIG analysis of CMS and *Redbook* files, 2012.

Limitations

We are not projecting these results to the population of pharmacies in November 2010. The acquisition cost data were for the largest invoices in November 2010 and may not necessarily be representative of average invoices from sampled pharmacies. We reported our findings in the aggregate and not for each drug because of the small amount of data for some drugs collected from sampled pharmacies. Therefore, we did not determine, for individual drugs, whether acquisition costs exceeded FULs. We did not verify the completeness or accuracy of self-reported acquisition cost data from responding pharmacies. We did not attempt to identify any discounts, rebates, or price incentives not reflected in the invoice prices.

Further, we did not verify the completeness or accuracy of CMS's FUL amounts. The FUL amounts based on AMPs provided by CMS have not been used for Medicaid reimbursement. The number of drugs included in each portion of the analysis varied depending upon the availability of data in each source for the time periods under review. The estimated reduction in November 2010 Medicaid expenditures was calculated using FUL amounts based on AMPs from 1 month and assumes that these FUL amounts would remain consistent throughout the quarter. If FUL amounts were higher or lower during the other months in the quarter, the savings associated with FUL amounts based on AMPs would have been different.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

FUL amounts based on published prices were more than four times total pharmacy acquisition costs

In November 2010, FUL amounts based on published prices were more than 4 times greater than sampled pharmacy acquisition costs for 601 drugs, in the aggregate. During that month, pharmacy acquisition costs for these drugs among sampled pharmacies totaled $139,949; pharmacy reimbursement by Medicaid for these drugs would have totaled $607,376 using the FUL amounts in effect at the time.[35]

FUL amounts based on AMPs were 61 percent lower than FUL amounts based on published prices, at the median

CMS's September 2011 draft FUL file and the fourth-quarter 2011 *Redbook* file included 518 drugs with FUL amounts based on both post-ACA AMPs and published prices. Implementing the AMP-based methodology required by the ACA would lower FUL amounts for most drugs. At the median, FUL amounts based on AMPs were 61 percent lower than FUL amounts based on published prices. FUL amounts were lower under the new methodology for 461 of the 518 individual drugs. Further, for 72 percent (330 of 461) of these drugs, the FUL amount based on AMP is less than half the FUL amount based on published prices. See Table 3 for the range of differences in FUL amounts.

Table 3: Comparison of FUL Amounts Based on AMPs to FUL Amounts Based on Published Prices

Difference Between FUL Amounts Based on AMPs and FUL Amounts Based on Published Prices	Number of Drugs
More than 50.01% lower	330
Between 25.01% and 50% lower	81
Between 0.01% and 25% lower	50
Total Drugs for which FUL amounts based on AMPs < FUL amounts based on published prices	*461*
Between 0.01% and 25% higher	21
Between 25.01% and 50% higher	9
More than 50.01% higher	27
Total Drugs for which FUL amounts based on AMPs > FUL amounts based on published prices	*57*
Total	**518**

Source: OIG analysis of 2011 FUL amounts.

[35]Actual Medicaid reimbursement for these drugs can be lower because of other cost containment measures, such as State MAC programs. This total does not include dispensing fees.

We also calculated the potential reduction in November 2010 Medicaid expenditures if reimbursement had been based on post-ACA FULs (i.e., FUL amounts based on AMPs) from that month. We estimate that Medicaid expenditures would have been 29 percent ($19 million) lower in that month had FUL amounts based on AMPs been used for reimbursement.[36, 37] Given that this estimate is based only on 36 States and includes only the 416 drugs associated with FUL amounts based on AMPs in CMS's draft file, total savings would likely be different.

Even with the reductions resulting from the new methodology, FUL amounts based on AMPs would still have exceeded pharmacy acquisition costs in the aggregate

Despite the reduction in proposed reimbursement for most drugs, post-ACA FUL amounts based on AMPs still exceed sampled pharmacy acquisition costs in the aggregate. For 328 drugs under review, FUL amounts based on AMPs were 43 percent higher than sampled pharmacy acquisition costs from November 2010, in the aggregate. During this period, pharmacy acquisition costs for these drugs among sampled pharmacies totaled $80,922; had acquisition costs for these drugs been based on post-ACA FULs (i.e., FUL amounts based on AMPs), expenditures would have totaled $115,812.[38, 39] In other words, the reduced FUL amounts required by the ACA are still greater than pharmacy acquisition costs in the aggregate.

CMS had not completed implementation of AMP-based FUL amounts as of August 2012

CMS's withdrawal of the previous FUL and AMP rules related to the DRA took effect in December 2010; the Federal injunction against the agency was lifted in the same month. As a result, CMS was able to begin implementation of the ACA-required FUL amounts based on AMPs by calculating the new amounts and issuing draft files for review. However, as of August 2012, FUL amounts are still based on published prices.

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[36] This estimate is based on 1 month of FUL amounts and assumes that they were consistent from 1 month to the next.

[37] This total is based on ingredient costs and utilization from 36 States with reported Medicaid utilization for the fourth quarter of 2010 and a simple formula for calculating dispensing fees (e.g., $5 for generic drugs). This total includes only the 416 drugs associated with an AMP-based FUL amount in CMS's November 2010 draft file. Additionally, this total represents one-third (i.e., 1 month) of the quarterly utilization.

[38] We are unable to compare AMP-based FUL amounts to pharmacy acquisition costs for individual drugs because of the sample size.

[39] This total does not include dispensing fees.

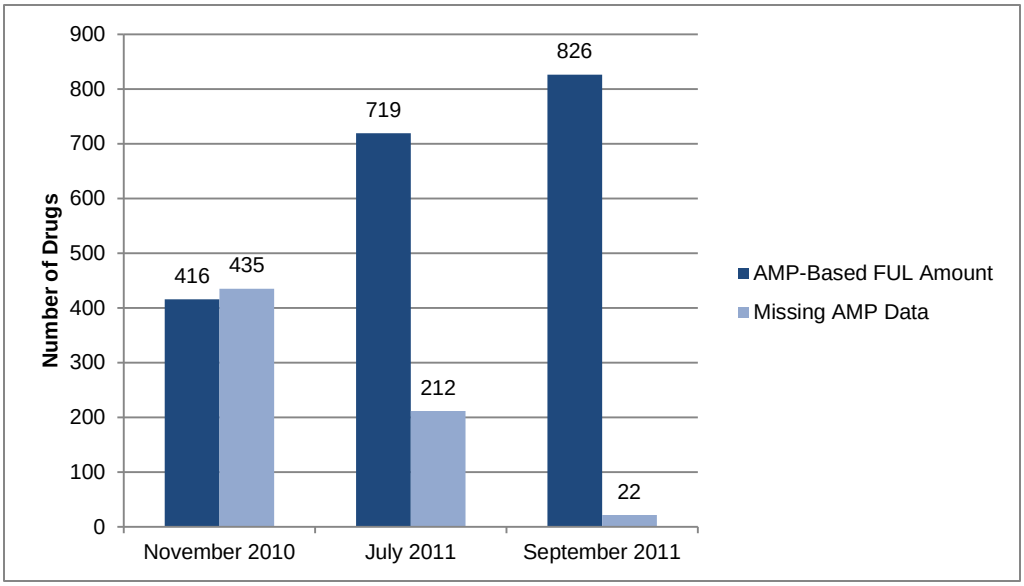
Manufacturer reporting of AMP data improved between 2010 and 2011

CMS's draft FUL files indicate that manufacturer reporting of AMP data improved substantially between 2010 and 2011. CMS staff attribute the increase to manufacturers' learning how to calculate post-ACA AMPs. Additionally, in accordance with an enforcement initiative announced in September 2010, OIG has begun imposing CMPs on certain manufacturers for not reporting pricing data (including AMPs) or reporting them late.

CMS's November 2010 draft file contained FUL amounts based on AMPs for 416 drugs. However, an additional 435 drugs were included in the draft file that did not have a FUL amount based on AMPs because manufacturers associated with at least one of the national drug codes (NDC) did not report AMP data.

The number of drugs associated with FUL amounts based on AMPs in the July and September 2011 draft files increased substantially (719 and 826 drugs, respectively). Conversely, the number of drugs that did not have a FUL amount based on AMP because of missing AMP data from November 2010 to September 2011 fell 95 percent (from 435 to 22 drugs). See Figure 1 for the difference in availability of FUL amounts based on AMPs between 2010 and 2011.

Figure 1: Availability of FUL Amounts Based on AMPs



Source: OIG analysis of CMS draft FUL files November 2010, July 2011, and September 2011.

CONCLUSION AND RECOMMENDATION

A series of OIG reports consistently found that the published prices used to set FUL amounts (and the related Medicaid reimbursement) frequently exceeded prices available in the marketplace by substantial margins. Our findings in this report indicate that FUL amounts based on published prices exceed not only sampled pharmacy acquisition costs but FUL amounts based on AMPs as well, albeit by a much smaller margin. We also found that despite the substantial reduction in proposed reimbursement, FUL amounts based on AMPs are still greater than sampled pharmacy acquisition costs, in the aggregate.

CMS has started to implement FUL amounts based on AMPs by releasing draft files, but has yet to complete implementation as required by the ACA. During this process, CMS has ensured transparency by releasing several draft files for public review and comment. Given the results of the body of OIG work and the potential reduction in Medicaid expenditures, we recommend that CMS:

Complete the Implementation of the Post-ACA AMP-based FUL Amounts

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendation and stated that it plans to implement FUL amounts based on AMPs in the near future. CMS noted that FUL reimbursement continues to be established in the aggregate and that States maintain the right to adjust reimbursement on a drug-by-drug basis. CMS also stated that 175 percent of weighted monthly AMPs should yield adequate reimbursement for pharmacies while achieving Medicaid cost savings.

We will continue to monitor CMS's efforts to implement FUL amounts based on AMPs as well as the relationship between pharmacy acquisition cost and FULs.

We did not make any changes to the report based on CMS's comments. For the full text of CMS's comments, see Appendix B.

APPENDIX A

Detailed Sampling Plan

We identified a stratified random sample of 120 traditional retail pharmacies from a sampling frame of 58,545 pharmacies selected by the Office of Inspector General's Office of Audit Services (OAS).[40] The sampling frame for this analysis includes all traditional retail pharmacies for 49 States and the District of Columbia (Arizona is not included)[41] that were open for business as of November 10, 2010, and listed in the National Council for Prescription Drug Programs dataQ Pharmacy Database file. The sampling frame excludes pharmacies identified as government, managed care, or nontraditional. We selected a stratified sample with 4 strata and selected 30 pharmacies from each stratum for a total of 120 pharmacies. See Table A-1 for a description of the sampling frame.

Table A-1: Sampling Frame

Stratum	Description	Universe Size
1	Urban independent	17,362
2	Urban chain	36,452
3	Rural independent	2,798
4	Rural chain	1,933
	Total	**58,545**

Source: OAS final amended sampling plan for *Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices* (A-06-11-00002).

[40] We are using data that were previously collected for work related to pharmacy acquisition cost and Medicaid reimbursement for prescription drugs. See *Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices* (A-06-11-00002), October 2011.

[41] Arizona had a managed care system for providing drugs to Medicaid beneficiaries at the time OAS collected pharmacy acquisition costs. After discussions with CMS, OAS chose to omit Arizona from its review.

APPENDIX B

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: AUG 0 8 2012

TO: Daniel R. Levinson
Inspector General

FROM: Marilyn Tavenner /S/
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Analyzing Changes to Medicaid Federal Upper Limit Amounts" (OEI-03-11-00650)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the OIG draft report entitled *"Analyzing Changes to Medicaid Federal Upper Limit Amounts."* This report provides an analysis of Medicaid pharmacy reimbursement comparing federal upper limit (FUL) amounts based on published prices to FUL amounts based on average manufacturer prices (AMP) currently in statute. Further, this report provides analysis of both published pricing and AMP-based FULs to pharmacy acquisition costs.

Prior to the enactment of the Deficit Reduction Act of 2005 (DRA), FULs were established based on commercial compendia pricing. The DRA revised section 1927 of the Social Security Act (the Act) to require that the Secretary establish the FULs using AMP, a pricing methodology based on actual sales data. However, CMS was enjoined from implementing the FULs using this methodology. The Affordable Care Act again revised the Act to require that the Secretary calculate the FUL at no less than 175 percent of the weighted average of monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drugs that are available for purchase on a nationwide basis. Beginning in September 2011, we issued draft FULs based on the current statutory requirements for review and comment only. In addition, we have posted the draft methodology used to calculate the FULs. These draft FUL prices are based on the most recently reported monthly AMP and AMP unit data, as required by statute.

OIG Findings

The OIG found that FUL amounts based on compendia prices were more than four times greater than sampled pharmacy acquisition costs for 601 drugs in the aggregate. This confirmed findings from prior OIG reports which consistently found that using compendia prices to set FUL amounts frequently exceeded prices available in the marketplace by substantial margins. OIG also found that the AMP-based FUL amounts were 61 percent lower than FUL amounts based on compendia prices at the median. OIG concluded that the AMP-based FUL amounts exceeded sampled pharmacy acquisition costs in the aggregate.

Agency Comments (continued)

OIG Recommendation

The CMS should complete the implementation of the post-ACA AMP-based FUL amounts.

CMS Response

We concur with the OIG recommendation, and plan to implement the final AMP-based FULs in the near future.

Further, the upper limit reimbursement continues to be established in the aggregate. States maintain their right to adjust reimbursement on a drug by drug basis to the extent that such an adjustment is consistent with the state plan and the state's reimbursement remains under the aggregate upper limit. Thus, using a factor of 175 percent of weighted monthly AMPs should yield adequate reimbursement for pharmacy providers, while achieving cost savings for the Medicaid program.

Again, we appreciate the opportunity to review and comment on this draft report.

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