Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

OUTLIER AVERAGE MANUFACTURER PRICES IN THE FEDERAL UPPER LIMIT PROGRAM

Daniel R. Levinson
Inspector General

September 2009
OEI-03-07-00740

Office of Inspector General

http://oig.hhs.gov

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EXECUTIVE SUMMARY

OBJECTIVES

1. To determine whether any Federal upper limit (FUL) drugs met the outlier criteria because of inconsistencies in how unit types were reported.
2. To determine whether the outlier average manufacturer prices (AMP) for FUL drugs are accurate.
3. To determine whether drugs with outlier AMPs are commonly available in the marketplace.

BACKGROUND

The Deficit Reduction Act of 2005 (DRA) made significant changes to Medicaid's FUL program, which is designed to ensure that the Federal Government acts as a prudent buyer by taking advantage of current market prices for multiple-source drugs. Under new DRA requirements, FUL amounts for most multiple-source drugs are to be based on 250 percent of the lowest reported AMP for each drug rather than 150 percent of the lowest price published in the national compendia of drug cost information. The DRA provisions additionally require AMP data to be made available to both States and the public.

As generally defined in statute, the AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. Manufacturers must provide the Centers for Medicare & Medicaid Services (CMS) with the AMP for each of their drug products on both a monthly and quarterly basis. If a product has been discontinued, the manufacturer must provide CMS with the termination date.

As reports by the Office of Inspector General (OIG) and the Government Accountability Office have previously shown, the lowest AMP for many FUL drugs falls below pharmacy acquisition costs even when multiplied by 250 percent. To address this issue, CMS announced plans to remove outlier AMPs from the FUL calculation. Pursuant to this outlier policy, CMS will exclude (with certain exceptions) the lowest AMP from the FUL calculation if it is more than 60 percent below the second-lowest AMP. According to CMS, the outlier policy is designed to ensure that two or more drug products can be purchased at or below the FUL amount.

In preparation for changes to the FUL calculation, CMS has taken steps to ensure that AMP data submitted by manufacturers are correct. In addition to requiring manufacturers to certify their pricing data, CMS contacted the manufacturers of certain drugs in March 2007 and encouraged them to review their AMP submissions for accuracy. However, very few manufacturers directly notified CMS as to whether their AMPs were accurate or inaccurate. CMS has also reminded manufacturers to report termination dates of discontinued drug products in a timely manner.

Although many Medicaid drug-related changes enacted by the DRA took effect on January 1, 2007, CMS has yet to use AMP data when establishing FUL amounts. In December 2007, the U.S. District Court for the District of Columbia issued a preliminary injunction to prevent the implementation of AMP-based FULs. In July 2008, the Medicare Improvements for Patients and Providers Act of 2008 directed CMS to refrain from implementing new FUL amounts or publicly disclosing AMP data until October 1, 2009. Until that time, AMPs will remain confidential and FULs will continue to be based on published prices.

This study examined 242 FUL drugs with AMPs that would have met CMS's outlier criterion if the changes enacted by the DRA had been in effect for January 2008. We determined whether outlier AMPs for these drugs had a unit of submission that differed from that of other AMPs associated with the drugs. In addition, we contacted the manufacturers of drug products with outlier AMPs and asked them to verify the accuracy of those AMP submissions. We also asked them whether the products in question were commonly available to the retail pharmacy class of trade.

FINDINGS

Because of unit-type discrepancies, some AMPs may not have actually been outliers. Of the 242 outlier AMPs identified by CMS, 18 may only have appeared as outliers because of discrepancies in the unit types for which AMPs were reported. Most of the outlier AMPs with inconsistent units of submission were reported in milliliters, whereas other AMPs for the same drugs were typically reported in units of "each" (which typically denotes a whole package, regardless of the amount of drug contained in that package). Because these 18 drugs may not have been outliers, we did not determine whether their AMPs were accurate or whether the drug was commonly available.

According to manufacturers, most outlier AMPs were accurate. We reviewed the accuracy of January 2008 AMPs for 185 of the 242 outlier drugs identified by CMS. Of these 185 outlier AMPs, manufacturers reported that 81 percent (150 of 185) were accurate, 18 percent (33 of 185) were inaccurate, and 1 percent (2 of 185) were potentially inaccurate. According to corrected AMP data provided by manufacturers, over half of the inaccurate AMPs (18 of 33) would have remained outliers under CMS's current policy, even with revised data. As a result, these 18 AMPs would still have been excluded from CMS's FUL calculations.

According to manufacturers, the vast majority of drug products with outlier AMPs were commonly available to the retail pharmacy class of trade. Manufacturers reported that 89 percent of outlier drugs included in this review (165 of 185) were commonly available to the retail pharmacy class of trade. Only 3 percent (6 of 185) were reported as not commonly available. For an additional 3 percent (6 of 185), the manufacturer could not state with certainty that the products were commonly available. The remaining 4 percent of outlier drugs (8 of 185) have been terminated by manufacturers and therefore should have been eliminated from FUL calculations before CMS's outlier policy was applied.

RECOMMENDATIONS

To ensure fair and adequate reimbursement, CMS plans to remove outlier AMPs from future FUL calculations. In January 2008, AMPs for 242 FUL drugs met CMS's definition of an outlier. This study demonstrates that a large majority of these outlier AMPs are, according to manufacturers, accurate and reflective of sales to the retail pharmacy class of trade. However, we found potential issues with approximately 20 percent of the outlier AMPs for FUL drugs. Some AMPs identified by CMS as outliers may only have appeared as such because of discrepancies in the unit of AMP submission. Furthermore, according to manufacturers, some outlier AMPs are not accurate and would no longer be outliers if revised data were used. Also, several outlier drug products are no longer sold by manufacturers and therefore should not be included in FUL calculations.

We recognize that CMS has taken steps to proactively resolve potential problems with FUL amounts based on AMP data. Furthermore, because CMS may set FULs based only on the data provided by

manufacturers, it is incumbent upon manufacturers to report accurate AMPs, termination dates, and units of measure for their covered outpatient drugs.

OIG supports CMS's continuing efforts to ensure the integrity of future FUL amounts based on AMPs and further recommends that CMS:

Examine the units of AMP submission for all FUL drugs before establishing FUL amounts.

Direct manufacturers to periodically examine their monthly AMP calculations to ensure accurate reporting of data.

Continue directing manufacturers to report termination dates for discontinued drug products as soon as they are known.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our first and third recommendations but did not explicitly concur or not concur with our second recommendation. Without further information from OIG regarding the causes of the inaccurate AMPs identified in this report, CMS does not believe that our second recommendation can be implemented. CMS believes it would not be beneficial to instruct manufacturers to reexamine their AMPs without giving them an indication of the specific problems that need to be addressed.

However, directing manufacturers to periodically review their monthly AMP calculations could ensure more accurate reporting of data, even without detailed guidance. As a result of OIG's work, some manufacturers examined and revised their monthly AMP calculations and did so without guidance on the problems that should be addressed. We will provide CMS with any explanations offered by manufacturers for their AMP revisions, including changes to lagged price concession data or chargeback smoothing methods. We will also provide CMS with details regarding how inaccurate AMPs for individual drug products changed as a result of manufacturers' corrections.

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1. To determine whether any Federal upper limit (FUL) drugs met the outlier criteria because of inconsistencies in how unit types were reported.
2. To determine whether the outlier average manufacturer prices (AMP) for FUL drugs are accurate.
3. To determine whether drugs with outlier AMPs are commonly available in the marketplace.

BACKGROUND

Pursuant to section 1927(e) of the Social Security Act (the Act), as amended by the Deficit Reduction Act of 2005 (DRA), P.L. No. 109-171, Medicaid FULs for most multiple-source drugs are to be based on 250 percent of the lowest AMP submitted by any manufacturer of the drug. As reports by the Office of Inspector General (OIG) and the Government Accountability Office (GAO) have shown, the lowest AMP for many of these drugs falls below pharmacy acquisition costs even when multiplied by 250 percent.[1] Pharmacy and patient groups have expressed great concern that this could impact Medicaid beneficiaries' access to certain products.[2]

In an attempt to address this issue, the Centers for Medicare & Medicaid Services (CMS) announced plans to remove outlier AMPs from the FUL calculation. Pursuant to 42 CFR § 447.514(c), published July 17, 2007, CMS will exclude the lowest AMP from the FUL calculation if it is less than 40 percent of the second-lowest AMP, with certain exceptions.[3] In other words, the lowest AMP is considered to be an outlier if it is more than 60 percent below the second-lowest AMP.

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[1] OIG, "Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program" (OEI-03-06-00400), June 2007 and GAO, "Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs" (GAO-07-239R), December 2006. These studies were conducted before changes to the definition of an AMP, such as the exclusion of prompt-pay discounts, took effect.

[2] An example includes the National Association of Chain Drug Stores, "Implications of Federal Medicaid Generic Drug Payment Reductions for State Policymakers," May 2007 Issue Brief.

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

According to CMS, the outlier policy is designed to help ensure that two or more drug products can be purchased at or below the FUL amount.[4] In OIG's report, "Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program" (OEI-03-06-00400), we found that 14 percent of the lowest AMPs met the outlier threshold in the second quarter of 2006.

Medicaid Reimbursement for Prescription Drugs

Currently, all 50 States and the District of Columbia (hereinafter referred to as States) offer prescription drug coverage under Medicaid. Medicaid beneficiaries typically obtain covered drugs from pharmacies. Pharmacies bill State Medicaid agencies using national drug codes (NDC), which are 11-digit identifiers that indicate a drug's manufacturer, product dosage form, and package size. Pharmacies are then reimbursed for these drugs by State Medicaid agencies. In calendar year 2007, Medicaid payments for prescription drugs totaled approximately $22 billion.[5]

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

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[4] 72 Fed. Reg. 39216 (July 17, 2007).

[5] Calculated using national summary data for 2007. This amount includes both Federal and State payments. Rebates collected by States under the Medicaid drug rebate program (section 1927 of the Act) were not subtracted from this figure. Because of problems with South Dakota's utilization data for the third quarter of 2007, payments for this State were excluded from the total. Data for additional States may not have been complete at the time of extraction. Therefore, the 2007 drug expenditures presented in this report may underestimate Medicaid's actual expenditures. National and State utilization data are available online at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/SDUD/list.asp. Accessed on September 17, 2008.

[6] 42 CFR § 447.331(b). On July 17, 2007, CMS issued a final regulation that would remove 42 CFR § 447.331 but include the unchanged substance of this section in a new section, 42 CFR § 447.512.

FUL program or State maximum allowable cost programs in setting reimbursement amounts.[7]

The FUL Program

The FUL program was created to ensure that the Federal Government acts as a prudent buyer by taking advantage of current market prices for multiple-source drugs. CMS publishes the FUL list, as well as any revisions, on its Web site. CMS establishes a FUL for specific forms and strengths for each multiple-source drug on the list.

Prior to the DRA, section 1927(e)(4) of the Act and 42 CFR § 447.332 required CMS to establish a FUL amount for a drug when three or more formulations of the drug were rated as therapeutically equivalent by the Food and Drug Administration and at least three suppliers of the drug were listed in current editions (or updates) of the published compendia of cost information for drugs available for sale nationally.

As originally set forth in 42 CFR § 447.332, FUL amounts are equal to 150 percent of the price published in a national compendia for the least costly therapeutically equivalent product that can be purchased by pharmacists in quantities of 100 tablets or capsules, plus a reasonable dispensing fee. For liquid drugs or drugs not typically available in quantities of 100, the FUL amount is based on the price for a commonly listed size of the product. States are required to meet FUL requirements only in the aggregate, i.e., a State may pay more than the FUL amount for certain products as long as these payments are balanced out by lower payments for other products.

Changes to FULs Under the Deficit Reduction Act of 2005

The DRA made significant changes to the FUL program. To be included on the FUL list under DRA requirements, a drug needs only two therapeutically and pharmaceutically equivalent versions and must be listed in a nationally available pricing compendium by a minimum of only two suppliers.[8] In addition, FUL amounts are to be based on 250 percent of the lowest reported AMP for each drug rather than 150 percent of the lowest price published in the national compendia.[9]

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[7] Many States have implemented maximum allowable cost programs to limit reimbursement amounts for certain drugs. Individual States determine the types of drugs that are included in their maximum allowable cost programs and the methods by which the maximum allowable cost for a drug is calculated.

[8] DRA §§ 6001(a)(1)(B) and (a)(3); 42 CFR §§ 447.514(a)(1)(i) and (ii).

[9] DRA § 6001(a)(2).

As generally defined in section 1927(k)(1) of the Act, an AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.[10] The AMP is generally calculated as a weighted average of prices for a manufacturer's package sizes of a drug sold during a given quarter and is reported for the lowest identifiable quantity of the drug as measured by one of eight unit types: capsule, tablet, milliliter, gram, each, suppository, transdermal patch, and injectable antihemophilic factor units.[11] [12] (For example, an AMP might be submitted for 1 tablet, 1 milliliter, or 1 gram.)

Pursuant to sections 1927(b)(3) and (k)(8) of the Act, manufacturers must provide CMS with the AMP for each of their NDCs on a quarterly basis, with submissions due 30 days after the close of each quarter.[13] If an NDC has been discontinued, the manufacturer must provide CMS with the product's termination date.[14] [15]

Under the DRA changes, manufacturers must also report AMPs on a monthly basis, with submissions due 30 days after the end of the month.[16] The DRA provisions additionally require CMS to disclose AMP data to both States and the public.[17]

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[10] Prior to the enactment of the DRA, manufacturers were required to deduct customary prompt pay discounts when calculating AMPs. However, section 6001(c)(1) of the DRA amended section 1927(k)(1) of the Act such that AMPs must be determined without regard to customary prompt pay discounts, effective January 2007. In December 2006, CMS instructed manufacturers to exclude customary prompt pay discounts from their AMP calculations as of January 2007.

[11] These eight unit types are specified by CMS in its "Definitions for Drug Product Data." Available online at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/proddata.pdf. Accessed on September 23, 2008.

[12] Because AMPs are averaged across different package sizes of a drug, the most commonly used package size will no longer be considered when computing new FUL amounts.

[13] Quarterly AMP data are collected for the purposes of calculating rebates owed to Medicaid by drug manufacturers.

[14] CMS, Drug Manufacturer Release Number 79 (August 15, 2007), and 72 Fed. Reg. 39142, 39207 (July 17, 2007).

[15] According to CMS, a drug's termination date depends on the reason it is being discontinued by the manufacturer. If a drug product is removed from the shelf immediately because of a health or safety concern, the termination date is the date removed. Otherwise, the termination date is the shelf life of the last batch sold. In either case, the manufacturer must continue reporting the product's AMP for 1 full year after its termination date.

[16] DRA § 6001(b)(1)(A).

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

FUL amounts established under the DRA are to be based on monthly, rather than quarterly, AMP data[18] and will derive from AMPs representing transactions that occurred 3 months previously.[19] For example, if new DRA requirements had been in effect during August 2008, FUL amounts published for that month would have been based on AMPs submitted by manufacturers for sales in May 2008.

In preparation for changes to the FUL calculation, CMS has taken steps to ensure that AMP data submitted by manufacturers are correct. For example, CMS requires manufacturers to certify their monthly and quarterly AMPs before submission. Furthermore, CMS contacted 100 manufacturers in March 2007 and encouraged them to review the accuracy of their AMP data for certain drugs. However, very few manufacturers directly notified CMS as to whether their AMPs were accurate or inaccurate.

Implementation of FUL Amounts Based on Average Manufacturer Prices

In July 2007, CMS published a final rule that, among other things, implemented the DRA provisions relating to FULs.[20] According to the outlier policy set forth in 42 CFR § 447.514(c), the lowest AMP will be excluded from the FUL calculation if it is less than 40 percent of the second-lowest AMP.[21] In other words, the lowest AMP is considered to be an outlier if it is more than 60 percent below the second-lowest AMP. Pursuant to 42 CFR § 447.514(c)(3), the outlier policy will not apply when the FUL group includes only the brand name drug and the first new generic or authorized generic drug that has entered the market. AMPs for terminated NDCs will also be excluded from new FUL calculations.[22]

Although the final regulation took effect on October 1, 2007, CMS has yet to use AMP data when establishing FUL amounts.[23] Initially, CMS planned to issue the first AMP-based FULs on December 30, 2007. However, on December 19, 2007, the U.S. District Court for the District of Columbia preliminarily enjoined the implementation of CMS's final

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

[19] CMS, Average Manufacturer Price/Federal Upper Limit Timeline, October 21, 2007.

[20] 72 Fed. Reg. 39142, 39244 (July 17, 2007).

[21] CMS solicited public comment on the new outlier policy described in its final regulation, with comments due in January 2008. However, as of November 2008, no additional information on CMS's outlier policy has been released.

[22] 42 CFR § 447.514(c)(1).

[23] As of November 2008.

rule concerning AMPs to the extent that it affects Medicaid reimbursement rates for retail pharmacies. In July 2008, the Medicare Improvements for Patients and Providers Act of 2008 (Improvements Act), P.L. No. 110-275, further delayed the implementation of new FULs based on AMPs. Pursuant to sections 203(a) and (b) of the Improvements Act, CMS must not take action to implement AMP-based FUL amounts or publicly disclose AMP data before October 1, 2009. Until that time, AMPs will remain confidential and FUL amounts will continue to be based on published prices.[24]

Previous Office of Inspector General Work Regarding the FUL Program and Average Manufacturer Prices

Previous OIG work found that the published prices used to set Medicaid FUL amounts before 2007 often greatly exceeded prices available in the marketplace.[25] Based in part on this work, the DRA required that Medicaid FULs be based on 250 percent of the lowest AMP rather than on 150 percent of the lowest price published in the national compendia.

In June 2007, OIG released a report assessing the potential effect of AMP-based FULs entitled "Deficit Reduction Act of 2005: Impact on the Medicaid FUL Program" (OEI-03-06-00400). According to this report, pre-DRA FUL amounts substantially exceeded estimated average pharmacy acquisition costs for 25 selected drugs in the second quarter of 2006 and would decrease considerably under the new calculation method established by the DRA.[26] In fact, pharmacies would only have been able to purchase 6 of the 25 reviewed drugs for less than the new FUL amount, on average. Furthermore, OIG found that the AMP used to set the FUL amount may be substantially lower than other AMPs associated with a drug. Of the 521 drugs on the FUL list, the lowest AMP for 14 percent was more than 60 percent below the second-lowest AMP.

Previous OIG work has also found that future Medicaid reimbursement could be affected by inconsistencies among the unit types used by manufacturers to report AMP data. According to a 2007 report, CMS's

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[24] Improvements Act § 203(a)(1).

[25] OIG, "Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices" (OEI-03-05-00110), June 2005 and "How Inflated Published Prices Affect Drugs Considered for the Federal Upper Limit List" (OEI-03-05-00350), September 2005.

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

unit of measure standards for the Medicaid drug rebate program are not always consistent with the unit standards established by the National Council for Prescription Drug Programs for retail transactions.[27] To address this issue, OIG recommended that CMS provide more specific guidance to manufacturers for certain units of measure, possibly including a detailed framework for selecting the appropriate unit type for a drug. CMS disagreed with the suggestion that broad guidance could resolve issues that differ on a case-by-case basis and stated that it would be virtually impossible to develop a framework or process that would effectively apply to all products.

METHODOLOGY

Scope

This study examined the accuracy of outlier AMPs that could affect new FUL amounts established under the DRA, as well as the availability of drug products with outlier AMPs. We examined only those drugs identified by CMS as having a lowest AMP that is more than 60 percent below the second-lowest AMP. This outlier criterion allows for only a single outlier for each FUL drug. It does not capture instances in which the second-lowest AMP also differs substantially from the other AMPs associated with the drug.

This study was not intended to address whether CMS should have an outlier policy, nor did we evaluate the effectiveness of CMS's current outlier policy. Furthermore, we did not examine whether pharmacies can acquire drugs with outlier AMPs for those outlier prices.

Data Sources

We obtained the file that CMS used to determine new FUL amounts for eligible drugs based on AMP data from January 2008.[28] This file contains information about multiple source drugs in the Medicaid program, including each drug's ingredients, strength, dosage, and route of administration; the NDC and January 2008 AMP for each individual drug product; therapeutic equivalency information; and whether the drug was eligible for inclusion on the FUL list under new DRA

[27] OIG, "Unit of Measure Inconsistencies in the Medicaid Prescription Drug Program" (OEI-05-07-00050), November 2007.

[28] Although the AMP injunction and the Improvements Act prevent CMS from implementing new FUL amounts based on AMPs, CMS continues to collect monthly AMP data from manufacturers and compute new FUL amounts based on those AMPs.

requirements. If a drug met the new requirements, the file indicated the FUL amount for the drug, as well as whether the drug had a lowest AMP that was more than 60 percent below the next lowest AMP.

Based on data from January 2008, CMS identified 1,332 drugs that met new FUL requirements specified in 42 CFR 447.514. These 1,332 drugs corresponded to 6,948 therapeutically equivalent 9-digit NDCs.[29]

AMPs identified as outliers by CMS. Of the 1,332 drugs in CMS's January 2008 FUL file, 242 (18 percent) were identified by CMS as having lowest AMPs that were more than 60 percent below the second-lowest AMPs. We identified the 9-digit NDCs associated with the lowest AMPs for each of these drugs.

Appendix A describes the extent to which outlier AMPs in CMS's file differed from the second-lowest AMPs.

Examining units of AMP submission for outlier drugs. While examining CMS's January 2008 FUL file, we became aware that the unit of AMP submission for any given FUL drug was not always consistent among manufacturers that sell the drug. For example, if Drug X is sold in 10-milliliter vials, manufacturer A might have submitted an AMP for 1 milliliter, whereas manufacturer B might have submitted an AMP for 1 vial. These two AMPs would not represent the same amount of the drug and therefore would not be comparable for the purposes of identifying outliers and establishing FUL amounts.

To determine the number of outliers affected by this issue, we reviewed the units of submission for each of the 242 outlier AMPs included in our study.[30] We identified outlier AMPs with a unit of submission that appeared to be different from that of other AMPs associated with the drug.

Data Collection

Using address information downloaded from CMS's Web site, we contacted the manufacturers of the 242 drug products with

[29] The first 9 digits of an 11-digit NDC represent the manufacturer and dosage form of the drug, and the last 2 digits represent the package size of the drug. As mentioned previously, an AMP is averaged across all package sizes for a drug. Because the 9-digit NDC is the same across all package sizes, manufacturers calculate AMPs for NDCs at the 9-digit level rather than the 11-digit level.

[30] The file CMS used to calculate FULs based on January 2008 AMPs did not contain units of submission for the AMPs. We therefore used the units of submission from CMS's first-quarter 2008 AMP file.

January 2008 AMPs identified as outliers by CMS.[31] Using written data collection instruments distributed by mail, we asked 40 manufacturers to verify the accuracy of their January 2008 outlier AMP submissions. If a manufacturer indicated that an outlier AMP was incorrect, we asked for corrected data.

To determine whether drug products with outlier AMPs are available in the marketplace, we also asked manufacturers whether the products in question are commonly available to the retail pharmacy class of trade, as defined in 42 CFR § 447.504(e).[32]

We made as many as three attempts to contact 40 drug manufacturers between May and July 2008. We received responses from 37 of the 40 manufacturers. The remaining three manufacturers never responded to our request despite what appeared to be accurate contact information.

Analysis of Manufacturer Responses

We aggregated manufacturers' responses regarding the accuracy of outlier AMPs and the availability of drug products associated with those AMPs. Outlier AMPs associated with the three nonrespondents were excluded from our analysis of manufacturers' responses, as were outlier AMPs with a unit of submission that appeared to be different from that of other AMPs associated with the drug.

If a manufacturer reported that an outlier AMP was incorrect, we determined whether the corrected AMP would still have been more than 60 percent below the second-lowest AMP. We also examined how FUL amounts would have been affected by the corrected AMPs provided by manufacturers.

Limitations

We did not independently verify whether FUL drugs in CMS's file actually met the requirements established under the DRA, nor did we independently determine which drugs had a lowest AMP that met

[31] Contact information for drug manufacturers that participate in the Medicaid drug rebate program is available online at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/10_DrugComContactInfo.asp. Accessed on March 12, 2008.

[32] For the purposes of this study and pursuant to 42 CFR § 447.504(e), "retail pharmacy class of trade" means any independent pharmacy, chain pharmacy, mail order pharmacy or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.

CMS's outlier criterion. Rather, we examined January 2008 AMPs for drugs that CMS had already identified as outliers.

Information regarding the accuracy of AMP data and the availability of drug products to the retail pharmacy class of trade was self-reported by manufacturers. Manufacturers were not required to furnish documentation demonstrating the way in which the outlier AMPs were calculated, nor were they required to provide sales data supporting the availability of drugs. However, each respondent was asked to provide a signed statement certifying that the data provided was true and accurate to the best of his or her knowledge.

Furthermore, AMPs are measures of central tendency for a range of prices available in the marketplace. Therefore, if a manufacturer indicated that a drug product with an outlier AMP was available to the retail pharmacy class of trade, it does not necessarily mean that all pharmacies could purchase the drug product for a very low price. Rather, it means that the drug product was widely available for purchase at prices that, when averaged, resulted in the outlier AMP reported to CMS.

Standards

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

Because of unit-type discrepancies, some AMPs may not have actually been outliers

Eighteen of the two hundred forty-two outlier drugs identified by CMS (7 percent) may only have appeared to be outliers because of discrepancies in the unit types for which AMPs were reported.[33] The lowest AMP for each of the 18 drugs had a unit of submission that differed from that of other AMPs associated with the drug and therefore may have represented a different amount of the drug. If manufacturers of these 18 drug products had submitted their AMPs using the same unit as other AMPs for the drug, the AMPs may not have been classified as outliers.

For example, Drug Y is sold in 20-milliliter vials by three different manufacturers.[34] One manufacturer submitted an AMP of $65 for a vial. Another manufacturer submitted an AMP of $60 for a vial. A third manufacturer submitted an AMP of $3 for 1 milliliter of the drug. The $3 AMP appears to be an outlier but only because it represents a different amount of the drug. If the third manufacturer had submitted an AMP for a vial rather than a milliliter, the AMP would have been $60 and would not have met any outlier criteria.

Most of the outliers with inconsistent units of submission were reported in milliliters

Lowest AMPs for 16 of the 18 drugs with unit-type discrepancies were reported in milliliters, whereas other AMPs for the same drugs were typically reported as "each." "Each" denotes a whole package, regardless of the amount of drug (milliliters, grams, etc.) contained in that package. According to CMS, manufacturers should report AMPs in units of "each" when the drug product is a powder-filled vial, ampule, syringe, packet, or a kit containing two or more different items dispensed as one product and sold at a single price. Some of the outlier AMPs reported in milliliters appear to represent powder-filled vials. To successfully compare those AMPs to the AMPs reported for each vial, it would first be necessary to identify the amount of liquid used to reconstitute the powder. This can sometimes be a difficult task.

[33] Because these 18 drugs may not have been outliers, we did not assess whether their AMPs were accurate or whether the drugs were commonly available.

[34] This example is based on data submitted for an actual outlier drug. However, because of the confidential nature of AMP data, we cannot publicly disclose the name of the drug.

According to manufacturers, most outlier AMPs were accurate

We reviewed the accuracy of January 2008 AMPs for 185 of the 242 outlier drugs identified by CMS.[35] Of these 185 products, manufacturers reported that 81 percent (150 of 185) were accurate. Another 18 percent (33 of 185) were reported as inaccurate by manufacturers. An additional 1 percent (2 of 185) were reported as potentially inaccurate.[36]

Over half of inaccurate AMPs would have remained outliers using corrected AMP data provided by manufacturers

Manufacturers for the 33 drug products with inaccurate outlier AMPs provided OIG with corrected AMP data for January 2008.[37] According to this corrected data, AMPs for over half (18 of 33) of the drug products would have remained outliers under CMS's outlier policy[38], even with the corrected prices. Because the corrected AMPs for these drugs were more than 60 percent below the second-lowest AMPs, they would still have been excluded from CMS's FUL calculations.

AMPs for the remaining drug products (15 of 33) would no longer have been outliers under CMS's policy. In other words, these AMPs would no longer have been more than 60 percent below the second-lowest AMP. Of the 15 drugs that no longer met CMS's outlier criteria, corrected AMPs for 12 were still the lowest AMPs.[39] Therefore, if manufacturers had reported their January 2008 AMPs correctly, these 12 drugs would have been used to establish FUL amounts.[40] As a result, FULs for the 12 drugs would have actually been lowered by an average of 29 percent.

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[35] The remaining 57 outlier drugs were excluded from our analysis because they had inconsistent units of AMP submission or the manufacturers did not respond to our request.

[36] According to the manufacturer for these two outlier drug products, data and programming errors had created inaccuracies in their monthly AMP calculations. At the time of our survey, the manufacturer did not know how or if those errors had affected the outlier AMPs identified in our study. We therefore classified these AMPs as "potentially inaccurate."

[37] Manufacturers for drugs with inaccurate outlier AMPs were not asked why the reported inaccuracies occurred. However, some respondents voluntarily provided explanations for the revisions, including changes to lagged price concession data or chargeback smoothing methods.

[38] As set forth in 42 CFR § 447.514(c).

[39] Although the corrected AMPs for these 12 drugs were still the lowest AMPs, most were approximately two to seven times higher than the January 2008 AMPs initially submitted by the manufacturers.

[40] Under the DRA, FUL amounts are calculated by multiplying the lowest AMP for the drug by 250 percent, with certain exceptions.

For the remaining three drugs, corrected AMPs were not the lowest AMPs. Therefore, FUL amounts for these three drugs would not have changed even if manufacturers had reported their January 2008 AMPs correctly.

According to manufacturers, the vast majority of drug products with outlier AMPs were commonly available to the retail pharmacy class of trade

CMS's outlier policy is designed in part to ensure that at least two drug products are available at or below the FUL amount.[41] According to manufacturers, the vast majority of drugs with outlier AMPs (89 percent, 165 of 185) were commonly available to the retail pharmacy class of trade.[42] Only 3 percent (6 of 185) of outlier drug products were reported as not commonly available. For another 3 percent (6 of 185), the manufacturer could not state with certainty that the products are commonly available.

According to manufacturers, the remaining 4 percent (8 of 185) of drugs that met CMS's outlier criteria have been terminated. In fact, one of these products was discontinued by the manufacturer almost 2 years ago. Pursuant to 42 CFR § 447.514 (c)(1), the AMP of a terminated NDC should not be used to establish a FUL amount. Therefore, these eight discontinued drug products should have been eliminated from FUL calculations before CMS's outlier policy was applied.

[41] 72 Fed. Reg. 39216 (July 17, 2007).

[42] The remaining 57 outlier drugs were excluded from our analysis because they had inconsistent units of AMP submission or the manufacturers did not respond to our request.

RECOMMENDATIONS

The DRA made significant changes to Medicaid's FUL program. Under new DRA requirements, FUL amounts for most multiple-source drugs are to be based on 250 percent of the lowest reported AMP for each drug rather than 150 percent of the lowest price published in the national compendia.

To ensure fair and adequate reimbursement, CMS plans to remove outlier AMPs from the FUL calculation. As set forth in 42 CFR § 447.514(c), CMS will exclude (with certain exceptions) the lowest AMP from the FUL calculation if it is more than 60 percent below the second-lowest AMP. This outlier policy is designed to ensure that at least two drugs are available at or below the FUL amount.

In January 2008, the lowest AMPs for 242 FUL drugs met CMS's definition of an outlier. This study demonstrates that a large majority of these outlier AMPs are, according to manufacturers, accurate and reflective of sales to the retail pharmacy class of trade.

However, we found potential issues with about 20 percent of the outlier AMPs for FUL drugs. Some AMPs identified by CMS as outliers may only have appeared as such because of discrepancies in the unit of AMP submission. Furthermore, according to manufacturers, some outlier AMPs are not accurate and would no longer be outliers if revised data were used. Also, several outlier drug products are no longer sold by manufacturers and therefore should not be included in FUL calculations.

We recognize that CMS has taken steps to proactively resolve potential problems with AMP-based FUL amounts. In addition to requiring manufacturers to certify their pricing data, CMS contacted the manufacturers of certain drugs in March 2007 and encouraged them to review their AMP submissions for accuracy. CMS has also reminded manufacturers to report termination dates of discontinued drug products in a timely manner.

We further recognize that under the DRA, CMS may set FULs based only on the data provided by manufacturers. Therefore, drug manufacturers play an important role in helping to ensure that new FULs are appropriate and must make certain that pricing data, units of measure, and termination dates are reported to CMS in an accurate and timely way. If and when CMS is permitted to publicly disclose AMP

data, the resulting transparency may lead to more accurate reporting of pricing data.

Consistent with past OIG recommendations, the DRA provisions are designed to make FULs more reflective of acquisition costs. However, for the new methodology to be effective, the AMP data on which FULs are based must be accurate and timely. We support CMS's continuing efforts to ensure the integrity of future FUL amounts based on AMPs and further recommend that CMS:

Examine the units of AMP submission for all FUL drugs before establishing FUL amounts

As noted in previous OIG work, inconsistencies in the units of AMP submission can have implications for future Medicaid reimbursement. For instance, CMS cannot effectively identify the lowest AMP for a FUL drug unless the units of AMP submission for each NDC are comparable. Therefore, to prevent inaccurate FUL calculations, CMS should ensure that the units of AMP submission are consistent across all AMPs for a drug. If any AMP has a unit of submission that differs from that of other AMPs associated with the drug, CMS should take steps to adjust the data before identifying outliers and setting FUL amounts. CMS should also notify manufacturers that submit AMPs using potentially inconsistent or inappropriate units of submission and request that they submit corrected information.

Direct manufacturers to periodically examine their monthly AMP calculations to ensure accurate reporting of data

In response to our study, a number of manufacturers reexamined and revised their monthly AMP calculations. Such changes could significantly impact FUL amounts for multiple-source drugs. Therefore, CMS should direct all manufacturers with rebate agreements to periodically reexamine their monthly AMP calculations and ensure that those calculations produce results that closely reflect the actual prices paid by AMP-eligible customers during each monthly reporting period.

Continue directing manufacturers to report termination dates for discontinued drug products as soon as they are known

Pursuant to 42 CFR § 447.514 (c)(1), the AMP of a terminated NDC should not be used to establish a FUL amount beginning with the first day of the month after the actual termination date reported by the manufacturer. Therefore, CMS should ensure that terminated drug products are not included in FUL calculations. Although manufacturers are ultimately responsible for reporting termination dates for their

drugs, CMS may wish to consult alternate sources when obtaining information about discontinued NDCs, such as different drug-pricing compendia. If CMS finds evidence that a product has been discontinued, it could specifically direct the manufacturer to report a termination date for that product.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our first and third recommendations, which concerned units of AMP submission and drug termination dates. Although CMS appreciated our second recommendation, which addressed the accuracy of manufacturers' monthly AMP calculations, the agency did not explicitly concur or not concur. Rather, CMS stated that it does not believe that this recommendation can be implemented without further information from OIG. Specifically, according to CMS, OIG neither characterized the nature of AMP inaccuracies identified in this report nor confirmed the accuracy of corrected AMPs. CMS further noted that when it asked certain manufacturers to review their AMPs for accuracy in March 2007, the respondents confirmed that their AMPs were correct. CMS also reiterated that manufacturers must certify their AMP data upon submission. Based on its previous experience and without additional information from OIG regarding the specific problems that should be addressed, CMS believes it would not be beneficial to instruct manufacturers to reexamine their AMPs.

OIG's second recommendation sought to address our finding that 19 percent of outlier AMPs were identified by manufacturers as being inaccurate or potentially inaccurate, despite having been certified as correct when originally submitted to CMS. As a result of OIG's work, a number of manufacturers examined and revised their monthly AMP calculations and did so without guidance on the specific problems that should be addressed. Although the manufacturers that responded to CMS's March 2007 request confirmed that their AMP data were correct, CMS did not require manufacturers to reply and received responses from less than 20 percent of the manufacturers it contacted. The remaining manufacturers may have adjusted their monthly AMPs without directly notifying CMS. Directing manufacturers to periodically review their monthly AMP calculations could ensure more accurate reporting of data.

Because of the confidential nature of AMPs, we could not include in this report information on how individual AMPs changed as a result of manufacturers' corrections. Rather, we describe whether corrected AMPs still met CMS's outlier criteria and how corrected AMPs would have affected FUL amounts. However, based on CMS's response, we will provide the agency with details regarding the differences between original and corrected January 2008 AMPs for each affected drug. Furthermore, although we did not specifically ask manufacturers why the reported inaccuracies occurred, we note on page 18 that some respondents voluntarily provided explanations for the revisions, including changes to lagged price concession data or chargeback smoothing methods. We will provide CMS with any explanations provided by manufacturers for revisions to specific drug products.

We ask that, in its final management decision, CMS explicitly state whether it concurs with our second recommendation and what steps, if any, it will take to implement it.

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

APPENDIX ~ A

Differences Between the Lowest and Second-Lowest Average Manufacturer Prices for Outlier Drugs

On average, average manufacturer prices (AMP) for the 242 outlier drugs were 78 percent below the second-lowest AMPs. The lowest AMP for 43 of the outlier drugs was at least 90 percent below the second-lowest AMP, with 4 outlier AMPs being 99.99 percent below the next-lowest AMPs. For example, the lowest AMP for Drug X was $0.000001, while the second lowest AMP was $0.074444.

The table below describes the extent to which outlier AMPs differed from the second-lowest AMPs.

Extent to Which Outlier AMPs Were Below Second-Lowest AMPs

Percentage Below the Second-Lowest AMP	Number of Drugs With Outlier AMPs
60.00%–69.99%	78
70.00%–79.99%	65
80.00%–89.99%	56
90.00%–99.99%	43
Total	**242**

Source: Office of Inspector General's analysis of the January 2008 Federal upper limit file prepared by the Centers for Medicare & Medicaid Services, 2008.

APPENDIX ~ B

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: MAY 2 2 2009

TO: Daniel R. Levinson
Inspector General

FROM: Charlene Frizzera /S/
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Outlier Average Manufacturer Prices in the Federal Upper Limit Program" (OEI-03-07-00740)

Thank you for the opportunity to review and comment on the subject draft report. The purpose of this OIG report was to determine: (1) the effect of inconsistently reported unit types on outlier average manufacturer prices (AMPs) for Medicaid Federal upper limit (FUL) drugs, (2) the accuracy of outlier AMPs, and (3) the availability of drug products with outlier AMPS to the retail class of trade.

Under section 1927 of the Social Security Act, manufacturers are required to report certain drug product and pricing data to the Centers for Medicare & Medicaid Services (CMS), including the AMP and unit type of the drug (e.g., tablet, milliliter, gram). Under the Deficit Reduction Act of 2005 (DRA), FUL amounts for multiple source drugs are to be set at 250 percent of AMP for the least costly therapeutically equivalent drug. In accordance with CMS regulation, additional criteria would be used to calculate the FUL. One of these criteria is that drugs considered to be outliers would be excluded from this calculation. In accordance with the outlier policy set forth in 42 CFR 447.514, CMS would disregard the lowest AMP if it is more than 60 percent below the second lowest AMP in order to avoid a FUL being set below the cost at which the drug is nationally available.

The OIG notes that CMS has taken steps to assure that manufacturer-submitted AMP data is correct, including requiring certification of such data, and encouraging manufacturers to report data in a timely manner, including termination dates of discontinued drugs. The OIG also notes that the preliminary injunction issued by the U.S. District Court for the District of Columbia prevents the implementation of AMP-based FULs and State access to AMP data, and prohibits CMS from taking any actions to implement the AMP rule to the extent such action affects Medicaid reimbursement for such drugs. In addition, a moratorium in the Medicare Improvements for Patients and Providers Act of 2008 prohibits CMS from issuing AMP-based FULs until October 1, 2009.

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OIG Recommendation

CMS should examine the units of AMP submission for all FUL drugs before establishing FUL amounts.

CMS Response

We concur. In regard to the unit type discrepancies in the FUL drug groups, we will further review those FUL groups to determine what effect the different unit types have on the calculation of the AMP-based FUL.

OIG Recommendation

CMS should direct manufacturers to periodically examine their monthly AMP calculations and to ensure accurate reporting of data.

CMS Response

While we appreciate this recommendation, we do not believe we can implement this recommendation absent further information from the OIG. In March 2007, CMS contacted manufacturers whose submitted AMPs, when multiplied by 250 percent (per the DRA requirements), were below the pre-DRA FUL reimbursement. CMS requested that those manufactures review their AMPs for accuracy, but the manufacturers that responded confirmed their numbers were correct. Further, manufacturers are required to certify their pricing data upon submitting them to CMS, and manufacturer reporting is tracked by CMS on a monthly and a quarterly basis to identify manufacturer non-compliance.

The OIG reports that 81 percent of the AMPs were confirmed as correct. For the remaining AMPs, the OIG neither states what the changes in the AMP were, whether there were specific policies these manufacturers didn't understand that caused the AMPs to be reported incorrectly, nor confirmed that the manufacturers changed AMPs were correct.

Based on our previous experience and absent further information from the OIG as to what types of problems manufacturers are encountering in determining their AMPs, we believe it would not be beneficial to instruct manufacturers to re-examine their AMPs without giving them an indication of what problems in the calculation they should address. CMS will follow up with manufacturers if we determine- or the OIG provides further information- that there are specific problems manufacturers had in computing their AMPs.

OIG Recommendation

CMS should continue directing manufacturers to report termination dates for discontinued drug products as soon as they are known.

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CMS Response

We concur. We have issued guidance to labelers to report termination dates as soon as they are known and we will continue to do so. The "termination date" of a drug, as defined in the Medicaid Drug Rebate Program (MDRP) is unique to the Program, and when this information is submitted to CMS it is certified by labelers. Therefore, we do not believe that using alternate sources for this data field would be adequate for this purpose.

We appreciate the OIG's review of this part of the MDRP. We also appreciate the OIG's acknowledgement of our efforts to assure that the data submitted under this program is correct, including requiring the manufacturers to certify their data, asking manufacturers to review their AMP calculations, and timely reporting terminated drugs.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director of the Medicare and Medicaid Prescription Drug Unit.

Lauren McNulty served as the team leader for this study. Other principal Office of Evaluation and Inspections staff from the Philadelphia regional office who contributed include Eric Biersmith; central office staff who contributed to this report include Kevin Manley.