United States Government Accountability Office

Report to Congressional Requesters

December 2013

MEDICAID PRESCRIPTION DRUGS

CMS Should Implement Revised Federal Upper Limits and Monitor Their Relationship to Retail Pharmacy Acquisition Costs

This report was revised on February 6, 2014 to correct the omission of reprinting written comments from the Department of Health and Human Services (HHS) on a draft report. A copy of the HHS's written comments was inserted in appendix V.

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CMS Should Implement Revised Federal Upper Limits and Monitor Their Relationship to Retail Pharmacy Acquisition Costs

GAO Highlights

Highlights of GAO-14-68, a report to congressional requesters

Why GAO Did This Study

States reimburse pharmacies for covered outpatient prescription drugs dispensed to Medicaid beneficiaries. For certain multiple-source outpatient prescription drugs, federal matching funds that states receive to reimburse pharmacies are limited by FULs. In 2010, PPACA modified the FUL formula to better reflect pharmacy acquisition costs and thus more effectively control Medicaid expenditures. However, CMS has not yet implemented the PPACA formula and continues to use FULs that were published in September 2009. CMS currently publishes draft PPACA-based FULs. CMS also created the NADACs for states to consider when setting reimbursement rates.

You asked GAO to look at the NADAC and the PPACA-based FULs. This report (1) describes how CMS develops the NADACs and (2) examines how PPACA-based FULs compare to the NADACs. GAO compared draft FULs and NADACs for first quarter 2013 in aggregate across all multiple-source outpatient prescription drugs subject to the FUL. GAO also reviewed CMS documentation and interviewed CMS officials on how the NADACs are developed and PPACA-based FULs are calculated.

What GAO Recommends

GAO recommends that the CMS Administrator (1) expeditiously implement the PPACA-based FUL formula and (2) monitor the relationship between the PPACA-based FULs and the NADACs on an ongoing basis. HHS concurred with these recommendations.

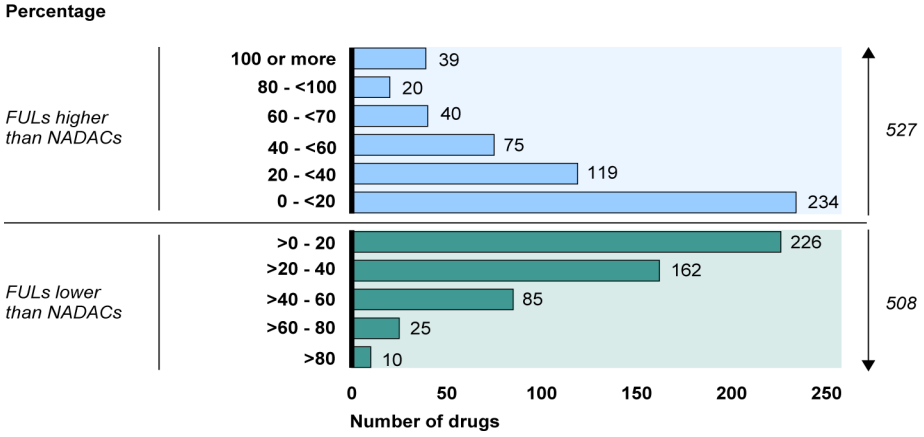
View GAO-14-68. For more information, contact John E. Dicken at (202) 512-7114 or dickenj@gao.gov.

What GAO Found

To develop a national benchmark for retail pharmacy acquisition costs of Medicaid covered outpatient prescription drugs—known as the National Average Drug Acquisition Cost (NADAC)—the Centers for Medicare & Medicaid Services (CMS) within the Department of Health and Human Services (HHS) surveys each month randomly selected retail community pharmacies for invoice data on their actual drug acquisition costs. CMS then calculates an average acquisition cost for each drug based on invoice data received from about 500 to 600 pharmacies. CMS officials expressed confidence in their current process, but noted that some limitations may exist. For example, CMS officials stated the extent to which NADACs reflect rebates and discounts is limited because most occur off-invoice or are not tied to a specific drug purchase. CMS has developed and published more than 5,000 NADACs, which CMS has estimated apply to more than 90 percent of the drug claims reimbursed by Medicaid.

GAO found that the total draft federal upper limits (FUL) amount based on the new formula under the Patient Protection and Affordable Care Act (PPACA) was about 1.4 percent lower than the total NADAC amount in aggregate for 1,035 outpatient drugs subject to the FUL in first quarter 2013.

Comparison of PPACA-Based FULs to NADACs, First Quarter 2013



Source: GAO analysis of CMS data.

GAO found large differences between the total PPACA-based FUL amount and the total NADAC amount for generic and for branded generic versions—brand-name drugs with other versions that can be substituted for one another—of the drugs subject to the FUL in first quarter 2013. GAO found that the total PPACA-based FUL amount for the generic versions was 19 percent higher than the total NADAC amount, but for the branded generic versions was 26 percent lower. GAO's work indicates that CMS is close to having a formula under which FULs would better reflect pharmacy acquisition costs, but continues to apply FULs that were calculated more than 4 years ago. Additionally, the relationship between PPACA-based FULs and NADACs may be affected by several factors, including rebates and discounts that are not reflected on pharmacy invoices. To determine whether GAO's early results of the relationship between the PPACA-based FULs and the NADACs holds over time will require continued monitoring by CMS.

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Abbreviations

AAC	Average Acquisition Cost
AMP	average manufacturer price
CMS	Centers for Medicare & Medicaid Services
DRA	Deficit Reduction Act of 2005
FUL	federal upper limit
HHS	Department of Health and Human Services
NADAC	National Average Drug Acquisition Cost
NDC	national drug code
OIG	Office of Inspector General
PCI	per capita income
PPACA	Patient Protection and Affordable Care Act
WAC	wholesale acquisition cost

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December 19, 2013

The Honorable Max Baucus
Chairman
Committee on Finance
United States Senate

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

Medicaid, a joint federal-state program that finances health care coverage for certain low-income individuals, spent an estimated $40.3 billion on outpatient prescription drugs in fiscal year 2012. State Medicaid programs do not directly purchase prescription drugs but instead reimburse pharmacies for covered prescription drugs dispensed to Medicaid beneficiaries. The federal government provides matching funds to each state for Medicaid expenditures, which cover a portion of the costs of these reimbursements.[1]

For certain multiple-source outpatient prescription drugs with three or more therapeutically and pharmaceutically equivalent versions, the federal government will provide matching funds for reimbursements only up to a maximum amount—known as a federal upper limit (FUL)—in order to control federal Medicaid expenditures on these drugs.[2] While state Medicaid programs may use different methods to reimburse retail pharmacies for covered prescription drugs,[3] for those drugs subject to the

[1]The federal government matches most Medicaid expenditures on the basis of a statutory formula known as the Federal Medical Assistance Percentage (FMAP). The FMAP is calculated based on each state's per capita income (PCI) in relation to the national PCI. For fiscal year 2013, states' FMAPs ranged from 50 to 73 percent.

[2]Therapeutically equivalent drugs are defined as those that can be substituted for one another with the full expectation that they will produce the same clinical effect and safety profile as each other. Pharmaceutically equivalent drugs must contain the same active ingredient(s) in the same dosage form and meet strength and other applicable standards.

[3]Each state administers its Medicaid program in accordance with a state Medicaid plan. These plans include methods used to reimburse pharmacies for outpatient prescription drugs.

FUL the federal government will only provide matching funds to the extent that a state's annual reimbursements do not exceed the sum of the FULs in aggregate.[4] As of September 2009, the formula used by the Centers for Medicare & Medicaid Services (CMS)—the agency within the Department of Health and Human Services (HHS) that oversees Medicaid—to calculate FULs was based on using 150 percent of the lowest price published in national drug pricing compendia and CMS continues to apply these FULs.[5]

Questions have been raised about whether FULs calculated using prices published in national compendia can effectively control Medicaid expenditures on drugs subject to the FULs because these prices do not reflect pharmacies' actual costs for acquiring these drugs.[6] For example, a 2005 report by the HHS Office of Inspector General (OIG) found that prices in the national compendia exceeded prices based on actual sales by as high as 70 percent.[7] In 2006, Congress required CMS to modify the formula used to calculate FULs. This modified formula was based on using 250 percent of a drug's average manufacturer price (AMP), which represents the average of prices paid to manufacturers and is typically

[4]This aggregate is determined by first multiplying the FUL by the number of units dispensed for each drug in a given state for a given year. The resulting dollar amounts are then added across all drugs subject to a FUL and the sum total represents the maximum amount eligible for federal matching funds. Therefore, it might be possible for a state Medicaid program to reimburse pharmacies at an amount above the FUL for certain drugs and not exceed the sum of FULs in aggregate if it also reimburses them at an amount below the FUL for other drugs.

[5]These prices are published in three national drug pricing compendia—First DataBank, Medi-Span, and Red Book. According to agency officials, CMS's legal authority to calculate FULs using this formula expired in September 2009. Accordingly, CMS currently continues to apply the FULs that were calculated and published as of September 2009.

[6]Retail pharmacies acquire prescription drugs from manufacturers and drug wholesalers. The price a retail pharmacy pays to these entities is known as a pharmacy's acquisition cost. Drug wholesalers (hereafter referred to as wholesalers) purchase bulk quantities of drugs from pharmaceutical manufacturers and then distribute them to pharmacies.

[7]See HHS OIG, *Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices* (Washington, D.C.: June 2005). More recently, the HHS OIG has found that FULs based on national compendia prices were more than four times higher than actual pharmacy acquisition costs. See HHS OIG, *A Comparison of Medicaid Federal Upper Limit Amounts to Acquisition Costs, Medicare Payment Amounts, and Retail Prices* (Washington D.C.: August 2009) and *Analyzing Changes to Medicaid Federal Upper Limit Amounts* (Washington D.C.: October 2012).

less than prices published in national compendia.[8] However, although CMS published a final rule to implement this formula, implementation did not occur due to a lawsuit filed by pharmacy associations concerned that the modified formula would result in reimbursement below their acquisition costs. These concerns were based in part on work by GAO and the HHS OIG, which generally found that FULs calculated using the modified formula were significantly lower than the average retail pharmacy's acquisition costs.[9] Reimbursing pharmacies below their acquisition costs could in turn affect pharmacies' ability to dispense outpatient prescription drugs to Medicaid beneficiaries and potentially reduce beneficiary access to drugs. In 2010, the Patient Protection and Affordable Care Act (PPACA) again modified the formula for calculating FULs to use no less than 175 percent of a drug's AMP and imposed an effective date of October 1, 2010.[10] CMS has not implemented the PPACA FUL formula yet, but calculates FULs using the formula and publishes these FULs in draft form.[11]

CMS also recently took steps to improve states' access to actual pharmacy acquisition cost data. In June 2010, a working group within the National Association of State Medicaid Directors recommended that CMS develop a single national price benchmark for pharmacy reimbursement based on the average of actual drug acquisition costs to assist states in

[8]Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 6001(a)(2), 120 Stat. 4, 54-55 (2006).

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

[10]Specifically, the revised formula uses the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple-source drugs that are available for purchase by retail community pharmacies on a nationwide basis. Pub. L. No. 111-148, § 2503(a), 124 Stat. 119, 310-312 (2010), as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA), Pub. L. No. 111-152, § 1101(c), 124 Stat. 1029, 1039, and Pub. L. No. 111-226, § 202, 124 Stat. 2389, 2394 (2010). For purposes of this report, references to PPACA include the amendments made by HCERA and Public Law No. 111-226.

[11]Throughout this report, references to PPACA-based FULs refer to FULs based on the PPACA FUL formula, but which are published in draft form. CMS publishes the PPACA-based FULs on a monthly basis on the federal Medicaid website. See http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html, accessed June 18, 2013.

setting their own reimbursement rates for outpatient prescription drugs. In response to this recommendation, CMS began surveying retail community pharmacies to collect actual prescription drug acquisition cost data to develop a new, publically available national price benchmark called the National Average Drug Acquisition Cost (NADAC) for Medicaid-covered outpatient prescription drugs.[12] In late 2012, CMS began publishing the resulting NADACs in draft form to help states assess how the use of the NADACs may affect their reimbursements to pharmacies.[13] CMS officials noted that states may choose to modify their drug reimbursement methodologies to use final NADACs by amending their Medicaid state plan.[14]

Because the NADACs are a new source of pharmacy acquisition cost data for states to consider in setting their reimbursements rates, it is important to understand how CMS develops the NADACs. Additionally, given questions about Medicaid FULs with regards to over- and under-reimbursing pharmacies for dispensing outpatient prescription drugs to Medicaid beneficiaries, it is important to understand how PPACA-based FULs compare to pharmacy acquisition costs. Accordingly, you asked us to examine the NADACs and the PPACA-based FUL formula. This report (1) describes how CMS develops the NADACs and (2) examines how PPACA-based FULs compare to the NADACs.

To describe how CMS develops the NADACs, we collected and reviewed CMS documentation on its methodology for calculating the NADACs, which included the process for surveying retail pharmacies, as well as comments stakeholders provided to CMS. We also reviewed NADACs published during the first quarter of 2013. In addition, we interviewed officials from CMS and Myers and Stauffer, LC (hereafter referred to as

[12]A retail community pharmacy is defined as a pharmacy that is licensed by a state and that dispenses medications to the general public at retail prices. The definition does not include pharmacies that dispense prescription medications to patients primarily through the mail, nursing home pharmacies, hospital pharmacies, and pharmacy benefit managers, among others.

[13]Throughout this report, references to NADACs refer to NADACs published in draft form unless noted otherwise. CMS publishes the NADACs on a weekly basis on the federal Medicaid website. See http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html, accessed June 18, 2013.

[14]Any changes to reimbursement methodologies for outpatient prescription drugs generally require CMS review and approval of an amendment to the state plan.

Myers and Stauffer), a public accounting firm, with which CMS contracted to develop the NADACs.

To examine how PPACA-based FULs compare to NADACs, we compared the PPACA-based FULs to the NADACs for first quarter 2013 in aggregate across all drugs subject to the FUL.[15] To make the aggregate comparison, we first determined a total FUL amount by multiplying each drug's FUL by its Medicaid utilization in the first quarter 2013—the most recent at the time we conducted our analysis—and summing these amounts across all drugs. We then followed a similar process to determine the total NADAC amount for the same drugs. Finally, we compared the total FUL amount to the total NADAC amount to determine the aggregate difference. In addition, we compared the PPACA-based FULs to the NADACs across generic versions and across branded generic versions—brand-name drugs with therapeutically equivalent versions, otherwise known as innovator multiple-source drugs.[16] We also compared the PPACA-based FULs to the NADACs for a subset of the 50 drugs with the highest Medicaid expenditures—accounting for 42 percent of all Medicaid drug expenditures for drugs subject to the FUL—and for the 50 drugs with the highest Medicaid utilization—accounting for 36 percent of all Medicaid prescriptions for drugs subject to the FUL—in the first quarter of 2013.

To assess the reliability of the NADACs, PPACA-based FULs, and Medicaid utilization data we used, we performed electronic testing for missing and inconsistent data and reviewed documents describing the methodology and quality assurance steps used for collecting and managing the data as well as calculating the NADACs and PPACA-based

[15]Drugs subject to the FUL accounted for more than $1.75 billion of Medicaid expenditures on outpatient prescription drugs in the first quarter 2013.

[16]In reporting AMP data to CMS for calculating the PPACA-based FULs, manufacturers designate each drug version as single-source, innovator multiple-source, or non-innovator multiple-source. A single-source drug is defined as a brand-name drug with no generic versions. A brand-name drug is a drug marketed under a proprietary, trademark-protected name. After any patent and market exclusivity for the brand-name drug expires, other drug companies may develop a therapeutic equivalent—generic—version. An innovator multiple-source is defined as a brand-name drug that has available generic versions. A non-innovator multiple-source drug is defined as a generic version. For purposes of this report, we refer to single-source drugs as brand-name drugs, innovator multiple-source drugs as branded generic versions, and non-innovator multiple-source drugs as generic versions.

FULs. We also interviewed agency officials knowledgeable about the data. We determined that the data were sufficiently reliable for the purposes of this report. (See app. I for more details on our methodology.)

We conducted this performance audit from July 2013 through December 2013 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Medicaid Coverage of Prescription Drugs

Outpatient prescription drug coverage is an optional benefit that all state Medicaid programs have elected to include in their Medicaid benefit packages. The outpatient prescription drugs covered by Medicaid include brand-name drugs and multiple-source drugs, the latter of which include branded generic versions and generic versions.

State Medicaid programs may use different methods for reimbursing pharmacies for outpatient prescription drugs dispensed to Medicaid beneficiaries. In general, states base their Medicaid reimbursements to a retail pharmacy for a covered outpatient prescription drug on the lowest of the following: a state's best estimate of retail pharmacies' acquisition costs for the drug; the usual and customary charge of the retail pharmacy that dispensed the drug; the state's maximum allowable cost for the drug, if applicable; or the FUL for the drug, if applicable.[17]

[17]The usual and customary charge for a drug is the full retail price that individuals without prescription drug coverage pay when purchasing drugs at a retail pharmacy. States that administer a maximum allowable cost program publish lists of selected drugs with the maximum prices at which the state will reimburse for those medications, which are often lower than the FUL for the same drugs. Pharmacies generally do not receive payments that are higher than the state-determined maximum allowable cost.

Medicaid FULs

Historically, CMS has calculated the FULs by grouping the therapeutically equivalent branded generic and generic versions of drugs, identifying the version with the lowest price published in national drug pricing compendia, and multiplying that price by 150 percent.[18] However, FULs do not apply to branded generic versions if the prescribing provider certifies that the specific brand is medically necessary for a particular patient.[19]

Congress has twice since 2006 enacted legislation that required a change to the FUL formula. Congress's first change to the FUL formula was in the Deficit Reduction Act of 2005 (DRA). Specifically, the DRA required FULs to be calculated as 250 percent of AMP for a drug's least costly therapeutic equivalent.[20] CMS issued a final rule in July 2007 to implement the DRA formula.[21] However, a lawsuit filed by two retail pharmacy industry groups—the National Association of Chain Drug Stores and the National Community Pharmacists Association—challenged the implementation of this rule primarily due to concerns that the revised formula would result in reimbursement well below retail pharmacies' acquisition costs. These concerns were, in part, based on

[18]Published prices included the average wholesale price, wholesale acquisition cost, and direct price. Average wholesale price is the average of the list prices that the manufacturer suggests wholesalers charge pharmacies. Wholesale acquisition cost is the manufacturer's list price for wholesalers or other direct purchasers before any rebates, discounts, allowances, or other price concessions. Direct price as published by First DataBank represents the manufacturer's published catalog or list price for a drug product to nonwholesalers.

[19]In this circumstance, the FUL does not apply and the state may use an alternative payment methodology for that branded generic version.

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

[21]72 Fed. Reg. 39142 (July 17, 2007). The final rule provided that federal reimbursement for drugs subject to a FUL could not exceed, in the aggregate, a reasonable dispensing fee plus an amount established by CMS in accordance with the revised FUL formula. The final rule also provided instructions for drug manufacturers in calculating and reporting AMPs, among other things.

work by GAO and the HHS OIG.[22] In December 2007, the U.S. District Court for the District of Columbia issued a preliminary injunction prohibiting CMS from implementing this final rule to the extent that it affected Medicaid reimbursement rates to retail pharmacies.[23] In July 2008, the Medicare Improvement for Patients and Providers Act of 2008 prohibited CMS from implementing the FUL provisions of the 2007 rule and provided CMS with the authority to issue FULs under the pre-DRA formula through September 2009. Accordingly, CMS stopped calculating and publishing FULs and continued to apply the FULs as calculated at that time.

In March 2010, legislation was again enacted that required a change to the formula for calculating the FUL. Under PPACA, FULs must be calculated as no less than 175 percent of the utilization-based weighted average of the most recent monthly reported AMP for a drug's pharmaceutical and therapeutic equivalents. Because PPACA specified a percentage multiplier for AMP-based FULs of at least 175, in implementing the modified formula the Secretary of HHS has the discretion to increase this percentage multiplier above that level. PPACA also changed the definition of AMP for outpatient prescription drugs and required the Secretary of HHS to implement a process to smooth out fluctuations in the AMPs reported by manufacturers.[24] PPACA also provided that these changes become effective as of October 1, 2010,

[22]In a 2006 report, we found that, for a sample of 77 drugs, the estimated AMP-based FULs using the DRA formula were on average 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. See GAO-07-239R. In a 2007 report, HHS OIG determined that, on average, pharmacies would have been able to purchase only 6 of 25 selected high-expenditure drugs for less than the AMP-based FULs using the DRA formula during the second quarter of 2006. See HHS OIG, *Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program* (Philadelphia, Pa.: June 2007).

[23]See *National Ass'n of Chain Drug Stores v. Health and Human Servs.*, 631 F. Supp. 2d 17 (D. D.C. 2009).

[24]Among other changes, PPACA specified that AMPs will be the average of prices paid to manufacturers for drugs available for purchase at retail community pharmacies on a nationwide basis. PPACA required the Secretary of HHS to implement a smoothing process for AMPs that is similar to the smoothing process used in determining average sales price of a drug or biologic covered under Medicare Part B. Medicare Part B covers certain physician, outpatient hospital, laboratory and other services, and medical equipment and supplies. Drugs obtained under Medicare Part B are those that are commonly administered by a physician or under a physician's close supervision in physicians' offices and hospital outpatient departments.

regardless of whether CMS issued final regulations by that date. Notwithstanding this effective date, CMS has continued to apply the FULs as calculated in 2009 rather than implementing the PPACA-based FULs.[25]

CMS has taken some steps towards addressing the PPACA-based FUL formula, including the issuance of a proposed rule in February 2012.[26] As part of this rule, CMS proposed using the minimum 175 percent multiplier in the calculation of FULs, which the agency determined would result in adequate reimbursement for pharmacies.[27] In calculating the PPACA-based FULs, CMS proposed relying on the designation as a brand-name drug, branded generic version, or generic version from the AMP data reported by manufacturers.[28] In addition, CMS proposed various calculations for smoothing fluctuations in the FULs, such as using the mean of the monthly weighted AMPs for a FUL product group over a specific period of time, as the agency found significant variability in the PPACA-based FULs from month to month. During the comment period for the proposed rule, CMS received a number of comments from a variety of stakeholders, such as independent pharmacy associations, chain drug stores, and drug manufacturers. Many stakeholders that commented on the application of the 175 percent multiplier to the weighted AMP noted the importance of the flexibility provided by PPACA for CMS to increase

[25]In an August 2013 report, the HHS OIG found that had the PPACA-based FUL amounts been implemented in January 2012 the aggregate reimbursement under the PPACA-based FULs would have been 22 percent lower than the aggregate reimbursement under the compendia-based FULs for 32 states. See HHS OIG, *Medicaid Drug Pricing in State Maximum Allowable Cost Programs* (Washington, D.C.: August 2013).

[26]77 Fed. Reg. 5318 (Feb. 2, 2012).

[27]In a 2010 report, we found that across 40 drugs FULs calculated based on the PPACA formula using the minimum 175 percent multiplier were 78 percent lower than FULs calculated based on compendia prices, but were still 35 percent higher than pharmacy acquisition costs, in the aggregate. See 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 (Washington, D.C.: Dec. 15, 2010). Similarly, in a 2012 report, the HHS OIG found that FUL amounts based on the PPACA formula using a 175 percent multiplier were 61 percent lower than FULs based on compendia prices, at the median, and 43 percent higher than pharmacy acquisition costs, in the aggregate. See HHS OIG, *Analyzing Changes to Medicaid Federal Upper Limit Amounts* (Washington D.C.: October 2012).

[28]CMS proposed excluding brand-name drugs from the FUL calculation because statutory provisions require the agency to only use multiple-source drugs in this calculation.

the 175 percent multiplier in certain circumstances. A number of stakeholders also recommended that CMS implement a smoothing process for the FULs.

In order to provide states with the opportunity to assess reimbursement under the PPACA-based FUL formula before it is implemented, CMS began publishing monthly PPACA-based FULs.[29] Specifically, CMS publishes two sets of PPACA-based FULs. One set, which has been available on a monthly basis since late 2011, is based on AMP data from a single month. In response to stakeholder requests that CMS smooth fluctuations in the single month FULs, a second set of PPACA-based FULs using AMP data from 3 months has also been available on a monthly basis since late 2012. To develop the 3-month rolling average, CMS calculates a weighted average of the most recent and prior 2 months' AMPs. CMS does not calculate this 3-month rolling average for any product group that did not meet the criteria for calculating a single-month FUL in any of the 3 months.[30] This approach could result in some drugs not being subject to FULs that otherwise would be if a single-month FUL were used.

NADAC

To develop the NADACs for outpatient prescription drugs, CMS entered into a contract with Myers and Stauffer to survey retail community pharmacies across the country on their drug acquisition costs. These acquisition costs are to reflect any discounts and rebates pharmacies may receive to the extent available.[31] CMS published a draft methodology of the survey process in May 2012 and began sending surveys to retail community pharmacies beginning in June 2012. CMS also held three webinars between June and December 2012 to provide additional

[29]According to CMS officials, the agency typically does not publish the PPACA-based FULs until about 2 months after the actual manufacturer sales on which the FULs are based have occurred. CMS officials indicated that this delay is due in part to the additional 30 days after the end of the month in which sales occurred that manufacturers have to report AMP data. For example, AMP data based on April manufacturer sales would be due to CMS by May 30 and then typically published in June.

[30]Criteria for calculating a FUL for a product group include, among others, having three or more suppliers, having three or more therapeutic equivalents, and having all labelers report and certify an AMP.

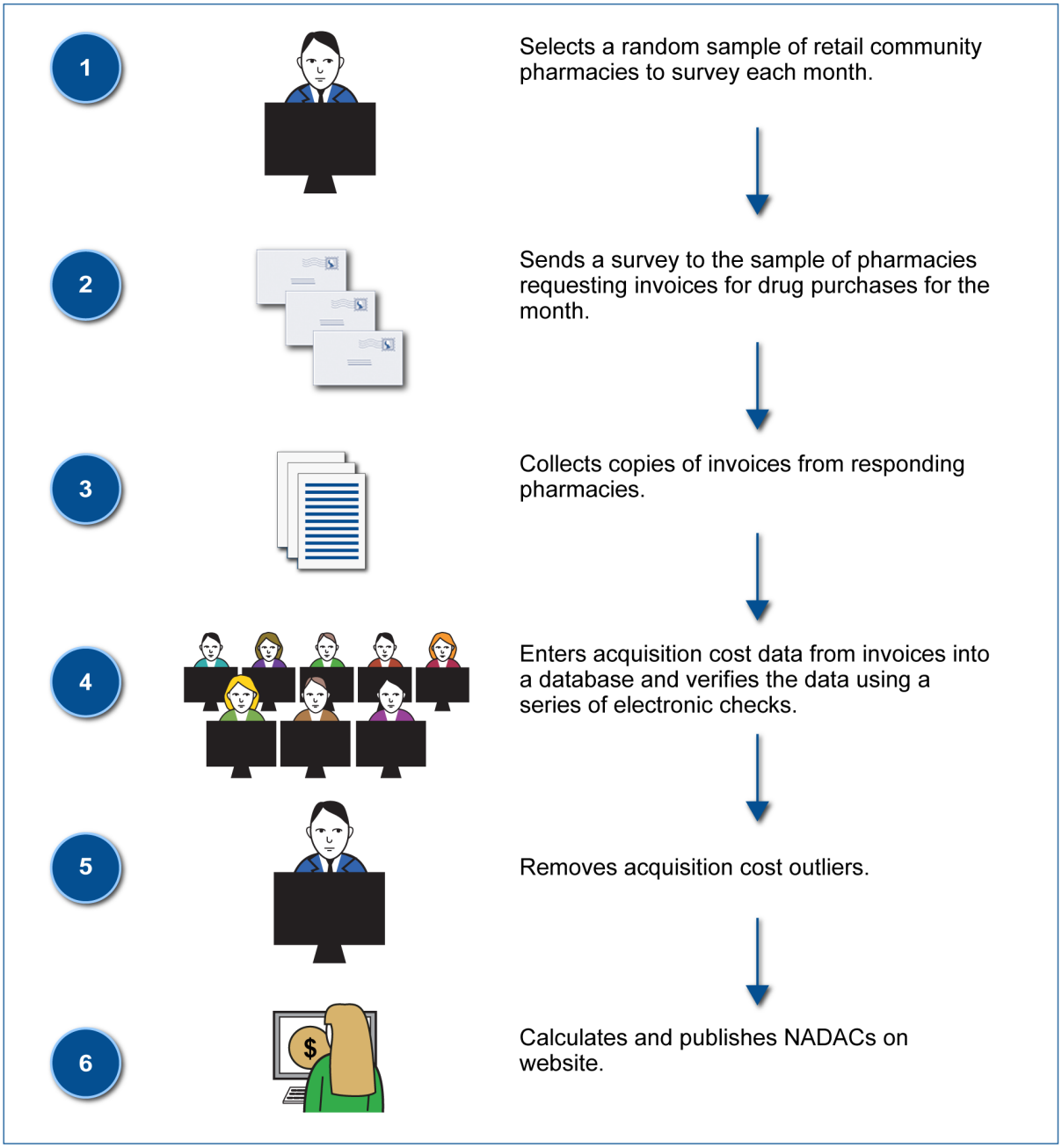
[31]Retail community pharmacies can receive discounts and rebates from manufacturers and wholesalers which sell drugs to retail pharmacies.

explanation of the draft methodology and receive feedback from stakeholders, such as state Medicaid programs and pharmacy industry groups. Stakeholders provided a range of comments seeking additional clarification and explanation regarding the draft methodology. CMS began publishing NADACs in draft form in late 2012.

CMS Develops NADACs by Surveying Retail Community Pharmacies for Invoice Data on Actual Acquisition Costs

CMS develops NADACs for outpatient prescription drugs by surveying a sample of retail community pharmacies, collecting invoices on actual drug acquisition costs, and calculating NADACs based on the invoice data. Figure 1 summarizes the process CMS follows for developing NADACs.

Figure 1: CMS Process for Developing National Average Drug Acquisition Costs (NADAC) for Outpatient Prescription Drugs



Sources: GAO analysis of CMS information; Art Explosion (images).

CMS develops NADACs by performing the following six steps:

1. *Selects a random sample of retail community pharmacies to survey each month*. Each month, CMS selects a simple random sample of approximately 2,500 retail community pharmacies out of more than 60,000 such pharmacies in the US to survey for acquisition cost data.[32] According to CMS officials, this sample is nationally representative because it reflects characteristics of all retail community pharmacies in the US—namely, the proportion of chain and independent pharmacies and the proportion located in urban and rural areas, which can have different acquisition costs.[33] In determining the sample size, CMS and Myers and Stauffer officials considered two main factors: (1) that 400 to 500 pharmacies are needed to respond in order to develop NADACs for most Medicaid covered prescription drugs and (2) to reach this target, at least 2,000 pharmacies need to be surveyed each month given anticipated response rates from pharmacies based on prior survey experiences. Myers and Stauffer officials also determined that the sample size would limit the burden on pharmacies to respond to the survey since the chances of an individual pharmacy being selected twice in the same year is less than 5 percent.
2. *Sends a survey to the sample of pharmacies requesting invoices for drug purchases*. CMS sends the survey to the sample of pharmacies requesting all invoices for drugs purchased from manufacturers and wholesalers during the reporting month. CMS and Myers and Stauffer officials noted that collecting actual invoices provided more reliable acquisition cost data than having pharmacies manually enter invoice costs into a survey and places a relatively low administrative burden on pharmacies. For each purchase, invoices must provide (1) the 11-digit national drug code (NDC) identifying the product purchased,[34]

[32]Data from the National Council for Prescription Drug Programs (NCPDP) are used to identify the universe of retail community pharmacies to sample. According to CMS and Myers and Stauffer officials, the NCPDP data provides the most comprehensive and up-to-date listing of retail community pharmacies.

[33]A chain pharmacy is generally defined as a pharmacy that belongs to a group of four or more pharmacies that are all under the same ownership. There are various definitions of independent pharmacies. In this report, we use the definition from the NCPDP, which defines an independent pharmacy as one to three pharmacies under common ownership.

[34]An NDC is a unique identifying prescription drug product number that is assigned in part by the Food and Drug Administration and registered and listed with it.

(2) the price paid, (3) the quantity purchased, and (4) purchase date. CMS and Myers and Stauffer officials indicated one limitation of using invoice data is that the extent to which rebates and discounts from wholesalers and manufacturers are reflected in the "price paid" is currently unknown. These officials also said some rebates and discounts may be included but, based on past experience, may not be significant compared to those occurring off-invoice or those not tied to a specific drug purchase.[35] To address this limitation, CMS is planning to examine off-invoice rebates and discounts more closely. CMS officials stated they plan to use a survey to collect additional information from retail community pharmacies regarding such rebates and discounts in the future.

3. *Collects copies of invoices from responding pharmacies*. According to CMS and Myers and Stauffer officials, approximately 500 to 600 pharmacies respond with invoice data to the monthly surveys. While this number of responses represents about 30 percent of the approximately 2,500 surveyed pharmacies, it meets or exceeds the target of 400 to 500 pharmacies that are needed to develop NADACs for most covered prescription drugs. However, unlike the sample of 2,500 surveyed pharmacies, the proportion of chain and independent pharmacies and the proportion rural and urban pharmacies that respond to the survey do not reflect the proportions of these pharmacies nationally. For example, chain pharmacies typically account for approximately 36 percent of survey responses, but account for about 65 percent of all retail community pharmacies. Similarly, independent pharmacies typically account for approximately 64 percent of survey responses, but account for about 35 percent of all retail community pharmacies.[36] While these differences are a limitation of the survey process, their impact on the NADACs is

[35]Rebates and discounts for retail community pharmacies can occur on a wholesaler's or manufacturer's entire line of products, rather than on a per-drug product basis, and the amounts of rebates and discounts may vary based on retail community pharmacies' negotiations with these entities.

[36]Urban pharmacies account for approximately 68 percent of survey responses but account for 77 percent of all retail community pharmacies. Rural pharmacies typically account for approximately 32 percent of survey responses but account for about 23 percent of all retail community pharmacies.

minimal based on analyses by Myers and Stauffer.[37] Myers and Stauffer will continue to monitor the proportion of chain and independent pharmacies that respond to the survey compared to the proportion of these pharmacies nationally to ensure acquisition cost data collected reflects national acquisition costs.

4. *Enters acquisition cost data from invoices into a database and verifies the data using a series of electronic and manual checks*. As CMS receives responses from surveyed pharmacies, CMS enters data from the invoices into a database and verifies the data. CMS uses a series of electronic and manual checks to determine whether the invoice data meet several verification criteria: (1) data are from the sampled pharmacies, (2) NDCs are valid and active, (3) purchase dates are from the appropriate month, (4) drug products are on the latest CMS rebate drug product data file,[38] (5) drug products have not been declared less-than-effective by the Drug Efficacy Study Implementation program,[39] (6) only one invoice cost per NDC per pharmacy, and (7) the purchase prices for all drug products reported from an individual pharmacy are not equal to or greater than its average wholesale prices.[40] If any of the criteria are not met, CMS excludes the data from consideration for calculating a drug's NADAC. As a final check, Myers and Stauffer staff manually compare data from the database to the submitted invoices to verify the accuracy and completeness of the data entered.

[37]Myers and Stauffer found that for chain pharmacies the average acquisition costs for generic versions were 1 to 2 percent lower, and for brand versions were about 1 percent higher, than costs for independent pharmacies. Myers and Stauffer also found that for rural pharmacies average acquisition costs for generic versions were about 2 to 3 percent higher, and for brand drugs were less than 1 percent higher, than costs for urban pharmacies. Due to these relatively low differences, Myers and Stauffer concluded the effect of the difference between the proportion of chain and independent pharmacies that respond to the survey and their proportion nationally was minimal.

[38]The rebate drug product data file contains the active outpatient prescription drugs reported by drug manufacturers for purpose of the Medicaid Drug Rebate Program.

[39]The Drug Efficacy Study Implementation program is a standard used by the Food and Drug Administration to categorize drugs according to their effectiveness—that is, whether a drug demonstrates a health benefit in a real-world situation.

[40]The average wholesale price is the average of the list prices that the manufacturer suggests wholesalers charge pharmacies and is a common benchmark used in pharmaceutical pricing and contracts. The acquisition costs pharmacies pay for a drug are typically less than average wholesale prices.

5. *Removes acquisition cost outliers*. CMS removes any acquisition costs that are outliers. To do this, CMS identifies each drug product as either brand or generic and then groups the brand and generic versions with the same active ingredient(s), strength, dosage form, and route of administration.[41] Within each grouping, CMS reviews the acquisition costs and removes those that are greater than two standard deviations from the mean unit cost of the grouping.
6. *Calculates and publishes NADACs on the CMS website*. CMS calculates NADACs for brand and generic versions once outliers are removed. CMS first calculates a simple average based on the acquisition cost data obtained through the survey. CMS then updates these amounts to reflect changes in the acquisition costs between the time data were collected and the time at which CMS is ready to publish NADACs.[42] CMS updates NADACs for brand versions on a weekly basis to reflect pricing changes in the wholesale acquisition cost (WAC), which are relatively proportional to changes in pharmacy acquisition costs according to CMS officials.[43] For example, if there is a 5 percent increase in the WAC of a particular brand version, retail community pharmacies' acquisition costs will also increase by 5 percent. By updating the NADACs weekly to reflect this correlation, CMS helps ensure the NADACs for brand versions reflect the most current acquisition costs at the time NADACs are published. Brand and generic versions are also reviewed and adjusted based on research initiated by pharmacy inquiries to the NADAC help desk—a service established to support pharmacies and state Medicaid agencies during the survey process and in response to notifications of drug price changes not reflected in the published NADACs. CMS

[41]NDCs are categorized as brand or generic based on the single-source, innovator multiple-source, and non-innovator multiple-source designations from the CMS outpatient drug file. Single-source and innovator multiple-source are categorized together as brand. An override process is used to re-categorize drug versions to reflect reimbursement policy used by the states. For example, an innovator multiple-source version may be re-categorized as generic if it is generally considered generic by states for reimbursement purposes. In some cases where there is a demonstrated variance in prices paid, package size may also be used to define drug groupings.

[42]NADACs are published approximately 6 to 8 weeks after requesting invoices from surveyed pharmacies.

[43]WAC is the manufacturer's list price for wholesalers before rebates and discounts and is published on a weekly basis. Changes in the WAC are measured as the relative percentage difference from the most current published WAC and the previously published WAC.

publishes the updated NADACs on a weekly basis on the Medicaid website.[44] CMS has developed about 5,000 NADACs that relate to more than 22,000 NDCs and that CMS estimated would apply to over 90 percent of drug claims reimbursed by Medicaid.[45]

While CMS and Myers and Stauffer officials acknowledged some limitations exist in developing the NADACs, they also expressed confidence in their current process as one that is both robust and representative of actual acquisition costs. In particular, Myers and Stauffer officials noted that each of the six steps in developing the NADACs included various quality assurance checks. For example, in addition to the systematic procedures for removing acquisition invoice cost outliers, a review team of pharmacists, accountants, and analysts also manually review data for reasonableness. This review may involve evaluating factors that influence drug prices, such as drug shortages and manufacturer price increases.

[44]Myers and Stauffer has performed an analysis of the margin of error associated with NADACs at a 95 percent confidence level—that is, the interval that would contain the actual mean unit costs for 95 percent of the samples that could have been drawn. Based on this analysis, NADACs for nearly all brand versions have a margin of error within plus or minus 5 percentage points of the mean unit cost. On average, the margin of error for all NADACs of brand versions was 0.5 percent. NADACs for all generic versions have a margin of error within plus or minus 10 percentage points of the mean unit cost. On average, the margin of error for all NADACs of generic versions was 2.4 percent. Myers and Stauffer also determined that NADACs for brand drugs are generally consistent with state calculated Average Acquisition Cost (AAC) data. An AAC program is similar to the NADAC program, but on a state level. Myers and Stauffer compared AAC data from Alabama—one of four states with an AAC program at the time—and NADACs. After adjusting for methodological differences such as smaller sample size and biannual surveys of retail community pharmacies, Myers and Stauffer found that the results for brand drugs were not significantly different.

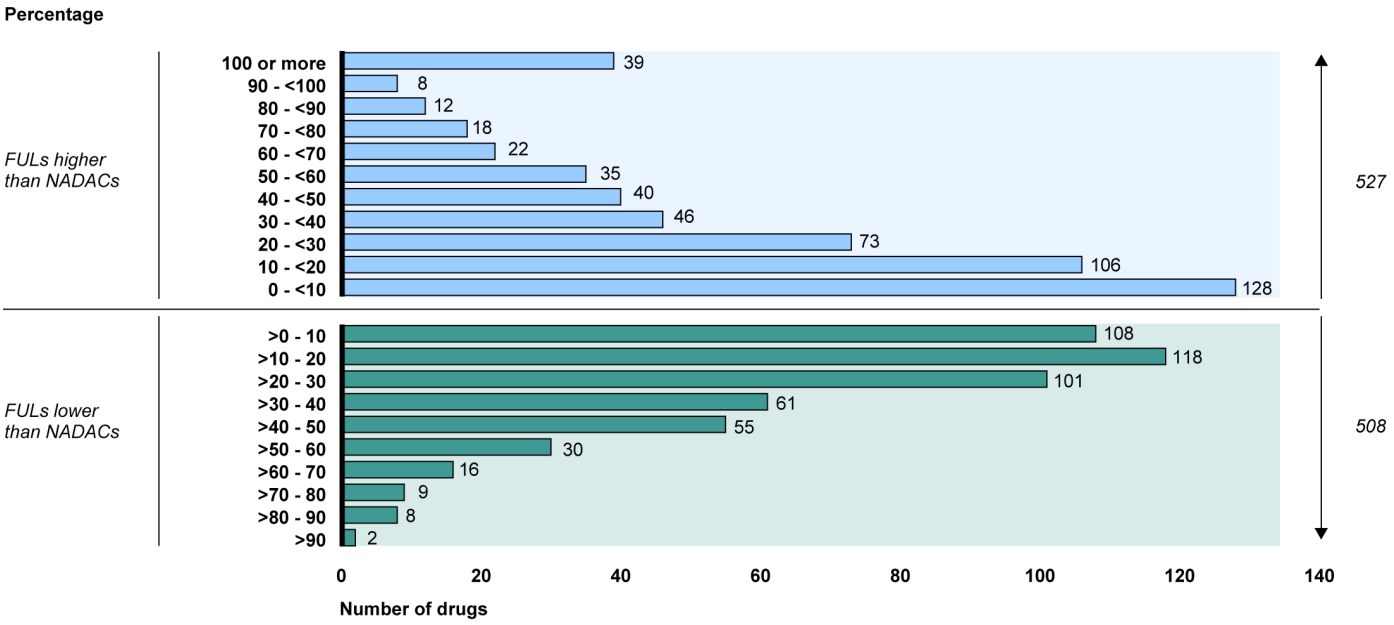
[45]Myers and Stauffer compared NADAC data and state utilization data to calculate the percent of claims reimbursed by Medicaid for which a NADAC had been developed. This analysis found that NADACs had been developed for about 93 percent of all brand-name claims and about 97 percent of generic claims. Myers and Stauffer expect to perform a similar comparison each year to determine the completeness of NADACs and its applicability to state Medicaid programs.

First Quarter 2013 PPACA-Based FULs Were Nearly Equal to NADACs across All Drugs in Aggregate, but Varied Greatly for Individual Drugs

Using the single-month PPACA-based FULs for all drugs subject to the FUL in the first quarter of 2013, we found the FULs were nearly equal to NADACs for these drugs in aggregate. Specifically, the total of the PPACA-based FUL amount for the 1,035 drugs included in our analysis was about 1.4 percent lower than the total NADAC amount for the same drugs.[46] Individually, PPACA-based FULs for slightly less than half—508—of the 1,035 drugs were lower than the NADACs for the same drugs. (See figure 2.) Conversely, PPACA-based FULs for slightly more than half—527—of the drugs were higher than the NADACs. PPACA-based FULs for individual drugs ranged from 96 percent lower than to 404 percent higher than the NADACs for the same drugs. In addition, PPACA-based FULs were slightly lower than NADACs for most of the 50 highest expenditure drugs, and nearly the same for most of the 50 highest utilization drugs we reviewed. (See app. II and III for additional details on our analysis comparing PPACA-based FULs and NADACs for the 50 highest expenditure and 50 highest utilization drugs.)

[46]Twenty-seven drugs were not included in our analysis due to either a lack of NADAC or utilization data.

Figure 2: Comparison of Single-Month PPACA-Based Federal Upper Limits (FUL) to National Average Drug Acquisition Costs (NADAC), First Quarter 2013



Source: GAO analysis of CMS data.

While we found that the PPACA-based FULs for the 1,035 drugs included in our analysis were nearly equally to NADACs in the aggregate, we found large differences for generic and for branded generic versions of these drugs. Specifically, we found that, in the aggregate, the total PPACA-based FUL amount for the generic versions of drugs was 19 percent higher than the total NADAC amount for these same versions. We also found that, in the aggregate, the total PPACA-based FUL amount for the branded generic versions of drugs was 26 percent lower than the total NADAC amount for the same versions. While PPACA-based FULs are published for branded generic and generic versions of drugs, they would not apply to branded generics that are prescribed as medically necessary per CMS's proposed rule. CMS officials stated that in practice, branded generic versions generally are not dispensed unless they are prescribed as medically necessary. However, Medicaid data do not indicate whether dispensed branded generic versions were prescribed as medically necessary and CMS officials noted that the agency is still considering how the PPACA-based FULs will apply to branded generic versions in the final rule.

Comparisons of PPACA-based 3-month rolling average FULs to NADACs resulted in findings that were generally within a few percentage points of the findings using the PPACA-based single-month FULs except for the comparison of branded generic versions. The total of the PPACA-based 3-month rolling average FUL amount for the drugs included in our analysis was about 4.4 percent lower than the total NADAC amount for the same drugs. However, we found that there were 123 drugs that had a single-month FUL but did not have a 3-month rolling average FUL.[47] We also found that, in the aggregate, the total PPACA-based 3-month rolling average FUL amount for the generic versions of these drugs was 23 percent higher than the total NADAC amount for these same versions. Conversely, we found that, in the aggregate, the total PPACA-based 3-month rolling average FUL amount for the branded generic versions of these drugs was 43 percent lower than the total NADAC amount for the same versions. (See app. IV for additional details on our analysis comparing 3-month rolling average PPACA-based FULs and the NADACs.)

Conclusions

FULs are intended to control federal Medicaid expenditures on outpatient prescription drugs that are subject to the FUL while ensuring beneficiary access to those drugs. However, CMS has not calculated and published FULs since September 2009 when its authority to use the pre-DRA formula expired. As a result, CMS continues to apply FULs that were calculated more than 4 years ago, a practice that has not ensured effective control of federal reimbursement for the drugs subject to the FUL. In the interim, PPACA modified the FUL formula and established an effective date of October 1, 2010, regardless of whether CMS had issued final regulations. In response, CMS has issued a proposed rule and determined that its proposed implementation of the PPACA-based FUL formula will provide for adequate reimbursement to pharmacies.

Our work, which found that PPACA-based FULs were nearly equal to the NADACs in the aggregate for all drugs subject to the FUL in first quarter 2013, indicates CMS is close to having a formula under which FULs better reflect pharmacy acquisition costs than they did under past formulas. However, the actual relationship between the PPACA-based

[47]For those 123 drugs, using the single-month PPACA-based FUL would allow states to use the FUL to set their drug reimbursements to pharmacies and allow the FUL to limit Medicaid expenditures, while the 3-month rolling average FUL would not.

FULs and NADACs may be affected by several factors. For example, although the NADAC provides a national benchmark for pharmacy acquisition costs based on invoices reflecting actual drug purchases from 500 to 600 pharmacies, the NADACs may vary from actual acquisition costs experienced among individual pharmacies across the country. Additionally, not all rebates and discounts are reflected on invoices collected during monthly surveys to pharmacies. If they were included, any applicable rebates and discounts would reduce the NADACs calculated by CMS, which would have at least somewhat reduced the slight difference in the PPACA-based FULs and NADACs we identified in first quarter 2013. Given this, we agree with CMS's plans to further study off-invoice rebates and discounts to understand how these may affect NADACs. Further, our analysis—which found that, on average, PPACA-based FULs exceeded NADACs for generic versions but not for branded-generic versions of drugs—indicates that the extent to which PPACA-based FULs will be applied to branded generic versions will also affect the aggregate relationship between the PPACA-based FULs and NADACs. There is also some uncertainty about how PPACA-based FULs and NADACs will compare over time, as our analysis was limited to the first full quarter of the newly published NADACs, the latest available data at the time we conducted our analysis. To determine whether our early findings regarding the relationship between the PPACA-based FULs and the NADACs hold over time will require ongoing monitoring by CMS.

Recommendation for Executive Action

We recommend the Secretary of HHS direct the Administrator of CMS take the following actions:

- Expeditiously implement the PPACA-based FUL formula to better control federal reimbursement for Medicaid covered outpatient prescription drugs; and
- Monitor the relationship between PPACA-based FULs and the NADACs on an ongoing basis to help determine whether PPACA-based FULs effectively control federal Medicaid expenditures without reducing beneficiary access to drugs subject to FULs over time.

Agency Comments and Our Evaluation

We provided HHS a draft of this report for comments. In its written comments, HHS concurred with our two recommendations and provided other remarks on our findings, as further discussed below.

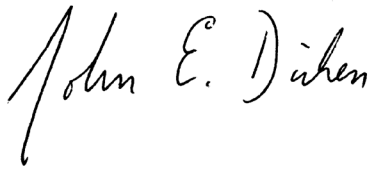
HHS concurred with our recommendation that CMS expeditiously implement the PPACA-based FUL formula to better control federal reimbursement for Medicaid covered outpatient prescription drugs. HHS stated that CMS announced in late November 2013 that it anticipates implementing the final PPACA-based FULs in July 2014, in order to provide states an opportunity to revise their reimbursement methodologies and adjust their reimbursement payment systems to incorporate the new PPACA-based FULs. HHS also concurred with our recommendation that CMS should monitor the relationship between PPACA-based FULs and the NADACs on an ongoing basis. HHS noted that CMS has been conducting analyses comparing PPACA-based FULs and NADACs and plans to continue these efforts.

HHS also commented on our findings, noting that CMS's analyses examining the relationship between PPACA-based FULs and NADACs found that, in aggregate, FULs were generally higher than NADACs. HHS indicated our inclusion of branded generic versions of drugs subject to the FUL in our analysis does not reflect that FULs typically do not apply to such versions because these versions are rarely dispensed unless prescribed as medically necessary. HHS also noted that our comparison of generic versions of drugs is consistent with HHS's analysis showing that the PPACA-based FULs were generally higher than NADACs. As we stated in our draft report, Medicaid data do not indicate whether dispensed branded generic versions were prescribed as medically necessary and thus do not identify specifically which dispensed branded generic versions would be subject to FULs. Further, in our discussion with CMS officials, they noted that the agency was still considering how the PPACA-based FULs would apply to branded generic versions in the final rule. Given this, we believe that our inclusion of branded generic versions is a more conservative approach to examining the relationship between the PPACA-based FULs and NADACs than entirely excluding these versions. We also reported information that separately analyzed PPACA-based FULs and NADACs for generic versions and branded generic versions. In its comments, HHS also noted that CMS finalized the NADACs in late November 2013 and suggested that states may want to consider using the NADACs as part of their reimbursement methodology.

HHS's comments are reproduced in appendix V. HHS also provided technical comments, which we incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of Health and Human Services. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

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



John E. Dicken
Director, Health Care

Appendix I: Methodology for Comparing Federal Upper Limits to National Average Drug Acquisition Costs

To examine how the Patient Protection and Affordable Care Act (PPACA)-based Medicaid Federal Upper Limits (FUL) compared to National Average Drug Acquisition Costs (NADAC), we compared first quarter 2013 PPACA-based FULs to NADACs both in aggregate and individually for (1) all drugs subject to the FUL, (2) branded generic versions of drugs subject to the FUL, (3) generic versions of drugs subject to the FUL, (4) a subset of the 50 highest expenditure drugs based on Medicaid reimbursement, and (5) a subset the 50 highest utilization drugs based on Medicaid prescriptions filled.

To conduct our analyses we used three data sources from CMS:

- **Draft PPACA-based FULs**: we examined PPACA-based single-month FULs for first quarter 2013.[1] We calculated a quarterly FUL price for each drug by taking the simple average of the 3 monthly FULs for that quarter. For purposes of this report, we consider a drug to consist of all the National Drug Codes (NDC) within a single FUL group.[2]
- **Draft NADACs**: for each of the drugs with a single-month FUL, we examined the corresponding NADACs published for first quarter 2013.[3] We calculated a quarterly NADAC price for each drug by taking a simple average of the weekly NADACs.
- **Medicaid Drug Utilization Data**: to examine how the single-month FULs compared to NADACs in aggregate across all drugs included in

[1]CMS publishes the draft single-month PPACA-based FUL files at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html, accessed June 18, 2013.

[2]An NDC is a unique identifying prescription drug product number that is assigned in part by the Food and Drug Administration and registered and listed with it. See http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm for the Food and Drug Administration's listing of NDCs, accessed November 4, 2013. Each drug may have more than one NDC, representing different manufacturers and different package sizes. Brand and generic versions of a drug also have different NDCs. The Food and Drug Administration assigns the first segment of the NDC, which identifies the labeler (i.e., the firm that manufactures, repackages, or distributes a drug). The labeler assigns the second and third segments. The second segment identifies a specific strength, dosage form, and formulation (e.g., 20 mg capsules) and the third segment identifies package size and type (e.g., 100 capsules in a bottle).

[3]CMS publishes the draft NADAC files at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html, accessed June 18, 2013.

our analyses, we used national Medicaid utilization data from first quarter 2013, which included both fee-for-service and managed care data, to weight our analyses. We also used this data to select the 50 highest expenditure drugs—accounting for 42 percent of all Medicaid expenditures for drugs covered by the FUL—and the 50 highest utilization drugs—accounting for 36 percent of all Medicaid prescriptions for drugs covered by the FUL. This utilization data was the latest available at the time of our analysis.

To compare the FULs to the NADACs in the aggregate, we (1) multiplied the FUL for each drug by its utilization and then summed all the FULs across the drugs, (2) multiplied the NADAC for each drug by its utilization and then summed all the NADACs across the drugs, and (3) compared the sum of the FULs to the sum of the NADACs. We repeated these same steps to examine how 3-month rolling average FULs compared to NADACs for first quarter 2013 in the aggregate.[4]

We also conducted additional analyses to test the sensitivity of our results for first quarter 2013. Specifically, (1) to determine the extent to which there may be month-to-month variation in our results, we reviewed how single-month FULs compared to NADACs for each month in first quarter 2013 and (2) since CMS typically does not publish the FULs until about 2 months after the actual manufacturer sales on which it is based have occurred, we compared single-month FULs that would have been available for states to use to reimburse pharmacies in first quarter 2013 if CMS had published FULs in final form on its website to NADACs.[5] The results of our sensitivity analyses were about the same as the results of our original analysis.

[4]The 3-month rolling average FUL is the weighted average of the single-month FUL for the current month and the 2 previous months for those drugs with a single-month FUL in all 3 months. For example, the March 2013 3-month rolling average FUL for a drug is the average of the January, February, and March 2013 single-month FULs for that drug. The 3-month rolling average FUL is intended to address problems with month-to-month fluctuations in the single-month FUL. CMS publishes the draft 3-month rolling average PPACA-based FUL files at http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html, accessed August 8, 2013.

[5]CMS officials said they instruct states to use the most recently published FULs for reimbursing pharmacies. For the purposes of our sensitivity analyses, we compared the November 2012, December 2012, and January 2013 single-month FUL data to January, February, and March 2013 NADAC data since these data most likely would have been available for states to use to reimburse pharmacies during first quarter 2013.

We reviewed all data for soundness and consistency and determined that they were sufficiently reliable for our purposes. Specifically, we performed electronic testing for missing and inconsistent data, reviewed CMS documents on the data, and spoke with CMS officials knowledgeable about the data. To test for missing and inconsistent data, we used 11 digit NDCs to identify a drug in our three data sources. We only included those NDCs in our analyses that had a published FUL in any month of first quarter 2013, a published NADAC in any month of first quarter 2013, and had utilization data for first quarter 2013. While there were 1,060 drugs with a single-month FUL in first quarter 2013, we dropped 25 drugs from our analyses because of a lack of NADAC data.[6] We also excluded those NDCs that did not meet all the criteria for having a FUL, including those NDCs for which CMS listed a FUL for a single source drug and that were not rated as being fully therapeutically equivalent.[7] We also excluded NDCs that listed different unit types across the FUL and NADAC data sets. We reviewed CMS documentation describing the methodology used to generate the data and the quality assurance steps that were followed for each data set. We also discussed the data with knowledgeable officials from CMS—specifically, we discussed the steps to collect and process the data, any limitations on the data's accuracy and completeness, and steps CMS takes to assure data quality.

There are limitations to our comparison of FULs to NADACs. We examined data representing only one quarter of 2013, which may not be representative of the relationship between FULs and NADAC for other months or quarters of that year or future years. Additionally, the extent to which off-invoice rebates and discounts are captured in the NADAC calculation is also a limitation and could lower the NADACs used in our analyses. Finally, all data used in this analysis are national and may not represent the experience of individual pharmacies and states across the country.

[6]We also excluded one drug, polyethylene glycol 3350, from our analysis because it had conflicting unit types in the FUL and NADAC files.

[7]The criteria for establishing a FUL include, but are not limited to, that there be at least three suppliers of a drug that all report and certify AMPs for the drug with a consistent unit type (e.g., tablet). Additionally, the drugs must not be generally considered to be inhalation, infusion, instilled, implanted, or injectable drugs and they must also be fully therapeutically equivalent (i.e., A-rated for therapeutic equivalence).

Appendix II: Comparison of Federal Upper Limits to National Average Drug Acquisition Costs, Top 50 Medicaid Expenditure Drugs

We compared the Patient Protection and Affordable Care Act (PPACA)-based single-month Federal Upper Limits (FUL) to the National Average Drug Acquisition Costs (NADAC) for the first quarter of 2013 for the 50 highest expenditure drugs subject to the FUL based on Medicaid reimbursement in first quarter 2013. In the aggregate, the total PPACA-based FUL amount for the 50 highest expenditure drugs was 5 percent lower than the total NADAC amount for the same drugs. We also found that 41 of the 50 highest expenditure drugs included branded-generic versions. Among the 50 highest expenditure drugs, PPACA-based FULs ranged from 69 percent lower to 64 percent higher than NADACs and 29 drugs had PPACA-based FULs lower than NADACs. Table 1 below summarizes the results of our comparisons for these high expenditure drugs.

Table 1: Comparison of Single-Month PPACA-Based Federal Upper Limits (FUL) to National Average Drug Acquisition Costs (NADAC) for the 50 Highest Medicaid Expenditure Drugs Subject to the FUL

Drug name and strength (dosage form)	Total number of Medicaid prescriptions	Total Medicaid reimbursement[a]	Percent that FUL is higher than (or lower than) NADAC	FUL group includes branded-generic versions[b]
Methylphenidate hydrochloride 36mg (extended release tablet)	296,096	$58,205,864	27.8%	Yes
Amphetamine aspartate; amphetamine sulfate; dextroamphetamine saccharate; dextroamphetamine sulfate 20mg (extended release capsule)	192,336	$42,655,407	(0.3%)	Yes
Methylphenidate hydrochloride 54mg (extended release tablet)	219,753	$38,812,213	28.1%	Yes
Amphetamine aspartate; amphetamine sulfate; dextroamphetamine saccharate; dextroamphetamine sulfate 30mg (extended release capsule)	165,996	$34,603,783	19.2%	Yes
Cefdinir 250mg/5ml (suspension)	349,245	$24,577,411	(54.2%)	No
Methylphenidate hydrochloride 27mg (extended release tablet)	148,954	$23,129,472	16.2%	Yes
Ziprasidone hydrochloride 80mg (capsule)	80,214	$23,077,344	(15.6%)	Yes
Amphetamine aspartate; amphetamine sulfate; dextroamphetamine saccharate; dextroamphetamine sulfate 10mg (extended release capsule)	119,591	$22,376,497	(3.9%)	Yes
Olanzapine 20mg (tablet)	74,736	$22,288,978	(43.9%)	Yes
Quetiapine fumarate 300mg (tablet)	122,409	$19,891,900	(50.9%)	Yes
Amphetamine aspartate; amphetamine sulfate; dextroamphetamine saccharate; dextroamphetamine sulfate 15 mg (extended release capsule)	97,754	$18,085,246	7.5%	Yes
Quetiapine fumarate 200mg (tablet)	138,133	$17,858,754	(49.5%)	Yes
Azithromycin 200mg/5ml (suspension)	798,759	$17,131,334	(16.8%)	Yes
Tacrolimus 1mg (capsule)	57,113	$17,117,891	20.0%	Yes
Quetiapine fumarate 400mg (tablet)	86,733	$15,882,157	(46.0%)	Yes
Montelukast sodium 5mg (chewable tablet)	438,743	$15,619,948	10.7%	Yes
Olanzapine 10mg (tablet)	83,794	$15,282,033	(50.1%)	Yes
Amoxicillin 400mg/5ml (suspension)	1,540,964	$14,321,528	(19.9%)	Yes
Olanzapine 15mg (tablet)	50,948	$13,643,832	(46.5%)	Yes
Acetaminophen; oxycodone hydrochloride 325mg; 10mg (tablet)	289,423	$13,456,537	20.3%	No

Drug name and strength (dosage form)	Total number of Medicaid prescriptions	Total Medicaid reimbursement[a]	Percent that FUL is higher than (or lower than) NADAC	FUL group includes branded-generic versions[b]
Amphetamine aspartate; amphetamine sulfate; dextroamphetamine saccharate; dextroamphetamine sulfate 25mg (extended release capsule)	65,484	$13,195,339	(5.1%)	Yes
Omeprazole 20mg (delayed release capsule)	1,169,782	$13,168,847	28.8%	Yes
Divalproex sodium 500mg (extended release tablet)	247,355	$13,043,598	28.4%	Yes
Quetiapine fumarate 100mg (tablet)	187,744	$12,682,377	(57.5%)	Yes
Azithromycin 250mg (tablet)	1,223,048	$12,513,992	(22.3%)	Yes
Clopidogrel Bisulfate 75mg (tablet)	357,703	$12,272,079	2.6%	Yes
Acetaminophen; hydrocodone bitartrate 325mg; 10mg (tablet)	460,950	$10,836,338	(24.4%)	No
Ziprasidone hydrochloride 60mg (capsule)	39,987	$10,487,768	(18.8%)	Yes
Permethrin 5% (cream)	191,998	$10,427,828	1.8%	No
Omeprazole 40mg (delayed release capsule)	563,859	$10,234,185	14.5%	Yes
Escitalopram oxalate 20mg (tablet)	226,560	$10,093,613	(30.8%)	Yes
Lamivudine; zidovudine 150mg; 300mg (tablet)	13,997	$10,031,093	53.8%	Yes
Pioglitazone hydrochloride 30 mg (tablet)	47,405	$9,888,358	(67.3%)	Yes
Polyethylene glycol 3350 17gm (powder)	442,756	$9,812,873	11.1%	No
Valacyclovir hydrochloride 500mg (tablet)	114,470	$9,481,547	(40.4%)	Yes
Oxycodone hydrochloride 30mg (tablet)	151,142	$9,471,666	1.9%	No
Amoxicillin; clavulanic acid 875mg; 125mg (tablet)	382,380	$9,316,296	(38.7%)	Yes
Modafinil 200 mg (tablet)	9,964	$9,309,238	(25.4%)	Yes
Gabapentin 300mg (capsule)	627,146	$9,219,813	40.9%	Yes
Clozapine 100mg (tablet)	72,320	$9,137,289	47.0%	Yes
Ziprasidone hydrochloride 40mg (capsule)	45,734	$9,125,666	(18.7%)	Yes
Cefdinir 125mg/5ml (suspension)	210,063	$9,021,313	(41.0%)	No
Fentanyl 100mcg (film)	25,415	$9,020,333	28.4%	Yes
Montelukast sodium 4 mg (chewable tablet)	253,879	$9,013,163	6.5%	No

Drug name and strength (dosage form)	Total number of Medicaid prescriptions	Total Medicaid reimbursement[a]	Percent that FUL is higher than (or lower than) NADAC	FUL group includes branded-generic versions[b]
Amphetamine aspartate; amphetamine sulfate; dextroamphetamine saccharate; dextroamphetamine sulfate 20 mg (tablet)	119,141	$8,255,920	(24.9%)	Yes
Pioglitazone hydrochloride 45mg (tablet)	34,830	$7,967,823	(68.9%)	Yes
Desmopressin acetate 0.2mg (tablet)	79,371	$7,805,000	(33.5%)	Yes
Valacyclovir hydrochloride 1gm (tablet)	77,215	$7,780,332	(38.5%)	Yes
Escitalopram oxalate 10mg (tablet)	171,992	$7,719,647	(48.4%)	Yes
Atorvastatin calcium 20mg (tablet)	192,973	$7,661,997	64.3%	Yes
Total	**13,158,357**	**$766,013,460**		
Total for all Medicaid drugs subject to the FUL[c]	**70,934,358**	**$1,754,665,444**		

Source: GAO analysis of CMS data.

[a]Total Medicaid reimbursement includes amounts states pay to pharmacies using their own methodologies.

[b]Branded-generic versions are brand-name drugs with therapeutically equivalent generic versions.

[c]This is the total for the 1,035 drugs with both FULs and NADACs in first quarter 2013.

Appendix III: Comparison of Federal Upper Limits to National Average Drug Acquisition Costs, Top 50 Medicaid Utilization Drugs

We compared the Patient Protection and Affordable Care Act (PPACA)-based single-month Federal Upper Limits (FUL) to National Average Drug Acquisition Costs (NADAC) for the first quarter of 2013 for the 50 highest utilization drugs subject to the FUL based on the number of Medicaid prescriptions filled in first quarter 2013. In the aggregate, the total PPACA-based FUL amount for the 50 highest utilization drugs was 1.8 percent lower than the total NADAC amount for the same drugs. We also found that 31 of the 50 highest utilization drugs included branded-generic versions. Among the 50 highest utilization drugs, PPACA-based FULs ranged from 54 percent lower to 258 percent higher than NADACs and 31 drugs had PPACA-based FULs higher than NADACs. Table 2 below summarizes the results of our comparisons for these high utilization drugs.

Table 2: Comparison of Single-Month PPACA-Based Federal Upper Limits (FUL) to National Average Drug Acquisition Costs (NADAC) for the 50 Highest Medicaid Utilization Drugs Subject to the FUL

Drug name and strength (dosage form)	Total number of Medicaid prescriptions	Total Medicaid reimbursement[a]	Percent that FUL is higher than (or lower than) NADAC	FUL group includes branded-generic versions[b]
Amoxicillin 400mg/5ml (suspension)	1,540,964	$14,321,528	(19.9%)	Yes
Azithromycin 250mg (tablet)	1,223,048	$12,513,992	(22.3%)	Yes
Omeprazole 20mg (delayed release capsule)	1,169,782	$13,168,847	28.8%	Yes
Tramadol hydrochloride 50mg (tablet)	1,056,066	$7,415,078	116.9%	Yes
Ergocalciferol 50000iu (capsule)	915,435	$4,932,530	(18.0%)	Yes
Acetaminophen; hydrocodone bitartate 500mg; 5mg (tablet)	893,728	$5,575,897	(1.1%)	No
Ibuprofen 800mg (tablet)	868,270	$4,749,196	12.7%	No
Amoxicillin 500mg (capsule)	827,419	$4,751,523	(11.5%)	No
Azithromycin 200mg/5ml (suspension)	798,759	$17,131,334	(16.8%)	Yes
Acetaminophen; oxycodone hydrochloride 325mg; 5mg (tablet)	780,009	$6,429,739	124.7%	No
Ibuprofen 600mg (tablet)	706,099	$3,276,242	(3.0%)	No
Folic acid 1mg (tablet)	662,268	$3,028,028	(26.8%)	No
Amoxicillin 250mg/5ml (suspension)	646,289	$5,112,039	(19.6%)	No
Ibuprofen 100mg/5ml (suspension)	640,338	$6,214,432	6.1%	Yes
Gabapentin 300mg (capsule)	627,146	$9,219,813	40.9%	Yes
Zolpidem tartrate 10mg (tablet)	613,169	$3,115,853	205.8%	Yes
Amlodipine besylate 10mg (tablet)	591,798	$3,417,952	38.4%	Yes
Simvastatin 20mg (tablet)	584,065	$3,878,650	258.4%	Yes
Hydrochlorothiazide 25mg (tablet)	584,039	$1,885,987	(25.5%)	No
Clonidine hydrochloride 0.1mg (tablet)	579,656	$3,752,068	7.0%	Yes
Omeprazole 40mg (delayed release capsule)	563,859	$10,234,185	14.5%	Yes
Sertraline hydrochloride 100mg (tablet)	515,116	$4,436,743	59.5%	Yes
Alprazolam 1mg (tablet)	499,203	$3,808,778	59.2%	Yes
Clonazepam 1mg (tablet)	489,458	$3,508,070	31.5%	Yes
Acetaminophen; hydrocodone bitartate 325mg; 10mg (tablet)	460,950	$10,836,338	(24.4%)	No
Lisinopril 20mg (tablet)	459,499	$2,510,837	14.1%	Yes
Amlodipine besylate 5mg (tablet)	458,272	$2,524,117	56.2%	Yes
Lisinopril 10mg (tablet)	455,919	$2,173,460	2.3%	Yes
Citalopram hydrobromide 20mg (tablet)	454,701	$2,635,369	62.5%	Yes
Simvastatin 40mg (tablet)	453,681	$3,346,908	134.7%	Yes

Drug name and strength (dosage form)	Total number of Medicaid prescriptions	Total Medicaid reimbursement[a]	Percent that FUL is higher than (or lower than) NADAC	FUL group includes branded-generic versions[b]
Clonazepam 0.5mg (tablet)	450,300	$2,720,148	76.2%	Yes
Fluoxetine hydrochloride 20mg (capsule)	446,655	$3,066,156	179.4%	Yes
Polyethylene glycol 3350 17gm (powder)	442,756	$9,812,873	11.1%	No
Montelukast sodium 5 mg (chewable tablet)	438,743	$15,619,948	10.7%	Yes
Trazodone hydrochloride 50mg (tablet)	420,164	$2,161,362	(0.3%)	No
Sertraline hydrochloride 50mg (tablet)	403,083	$2,880,428	34.1%	Yes
Cephalexin 500mg (capsule)	401,844	$3,053,676	(19.6%)	Yes
Trazodone hydrochloride 100mg (tablet)	393,268	$2,412,039	13.6%	No
Amoxicillin; clavulanic acid 875mg; 125mg (tablet)	382,380	$9,316,296	(38.7%)	Yes
Prednisone 20mg (tablet)	378,602	$1,794,632	38.5%	No
Metronidazole 500mg (tablet)	376,128	$3,569,294	(45.0%)	Yes
Alprazolam 0.5mg (tablet)	376,042	$2,358,658	51.7%	Yes
Promethazine hydrochloride 25mg (tablet)	375,489	$3,102,305	(43.4%)	No
Acetaminophen; codeine phosphate 300mg;30mg (tablet)	365,345	$2,526,844	(25.0%)	No
Clopidogrel bisulfate 75mg (tablet)	357,703	$12,272,079	2.6%	Yes
Cefdinir 250mg/5ml (suspension)	349,245	$24,577,411	(54.2%)	No
Dextromethorphan hydrobromide; promethazine hydrocholoride 15mg/5ml; 6.25mg/5ml (syrup)	339,225	$2,414,183	36.5%	No
Pantoprazole sodium 40mg (delayed release tablet)	328,358	$4,896,464	107.1%	Yes
Citalopram hydrobromide 40mg (tablet)	327,904	$1,879,229	59.2%	Yes
Prednisolone 15mg/5ml (syrup)	318,911	$2,256,691	(1.4%)	No
Total	**28,791,115**	**$292,596,249**		
Total for all Medicaid drugs subject to the FUL[c]	**70,943,358**	**$1,754,665,444**		

Source: GAO analysis of CMS data.

[a]Total Medicaid reimbursement includes amounts states pay to pharmacies using their own methodologies.

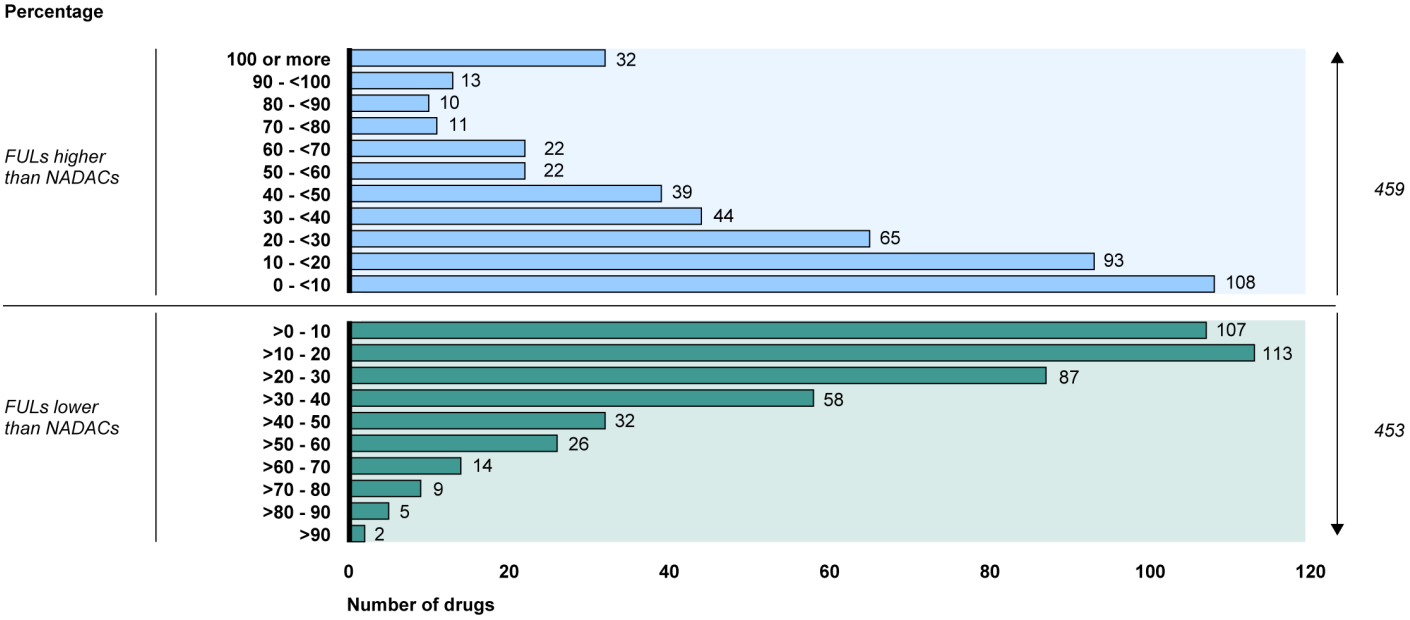
[b]Branded-generic versions are brand-name drugs with therapeutically equivalent generic versions.

[c]This is the total for the 1,035 drugs with FULs and NADACs in 2013.

Appendix IV: 3-Month Rolling Average Federal Upper Limits Compared with National Average Drug Acquisition Costs

We found that, in aggregate, the total Patient Protection and Affordable Care Act (PPACA)-based 3-month rolling average Federal Upper Limit (FUL) amount was 4.4 percent lower than the total National Average Drug Acquisition Costs (NADAC) amount for 912 drugs included in our analysis.[1] We found that PPACA-based 3-month rolling average FULs were higher than the NADACs for 459 drugs and lower than the NADACs for 453 drugs. Figure 3 shows the number of drugs with 3-month rolling average PPACA-based FULs higher and lower than NADACs for the same drugs.

Figure 3: Comparison of PPACA-Based 3-Month Rolling Average Federal Upper Limits (FUL) to National Average Drug Acquisition Costs (NADAC), First Quarter 2013



Source: GAO analysis of CMS data.

PPACA-based 3-month rolling average FULs were lower than NADACs for most of the 50 highest expenditure drugs, but higher for most of the 50 highest utilization drugs we reviewed. In the aggregate, the total PPACA-based 3-month rolling average FUL amount for the 50 highest expenditure drugs was 0.6 percent higher than the total NADAC amount

[1]There were 123 drugs that had a single-month FUL but did not have a 3-month rolling average FUL.

for the same drugs. Among the 50 highest expenditure drugs, PPACA-based 3-month rolling average FULs ranged from 40 percent lower to 113 percent higher than NADACs and 29 drugs had PPACA-based FULs lower than the NADACs. Our analysis of the 50 highest utilization drugs found that, in the aggregate, the total PPACA-based FUL amount was 6.2 percent higher than the total NADAC amount for the same drugs. Among the 50 highest utilization drugs, PPACA-based 3-month rolling average FULs ranged from 47 percent lower to 122 percent higher than NADACs and 31 drugs had FULs higher than NADACs.

Appendix V: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

DEC 9 2013

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

Dear Mr. Dicken,

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Medicaid Prescription Drugs: CMS Should Implement Revised Federal Upper Limits and Monitor Their Relationship to Retail Pharmacy Acquisition Costs" (GAO-14-68).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE (GAO) DRAFT REPORT: "MEDICAID PRESCRIPTION DRUGS: CMS SHOULD IMPLEMENT REVISED FEDERAL UPPER LIMITS AND MONITOR THEIR RELATIONSHIP TO RETAIL PHARMACY ACQUISITION COSTS" (GAO-14-68)

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

CMS finalized the National Average Drug Acquisition Costs (NADAC) on November 27, 2013 and notified states that it expects to finalize Federal Upper Limits (FUL) in July 2014. At that time, CMS also would anticipate discontinuing the previous FULs. In notifying states of the intent to finalize FULs, CMS notes its analysis shows that quarterly aggregate state payments using either the monthly average manufacturer price (AMP) based FUL or the 3-month rolling average FUL are generally above those payments using the NADAC pricing. Therefore, CMS also expects that the use of the NADAC would meet the FULs aggregate upper limit. States may want to consider the use of the NADAC as a reimbursement methodology; however, CMS notes that a state must submit a state plan amendment in accordance with the state plan requirements if it decides to use NADACs.

GAO's analysis of the FULs and NADACs supports the position in the paragraph above. The appropriate comparison between the FULs and the NADAC would be for the generic versions of the drugs, where GAO confirms that the FULs prices exceed the NADAC, for the following reason:

While CMS is required to include the brand name drug in the calculation of the FUL for a drug group, the FUL does not generally apply to that brand name drug. Instead, a brand name drug for which there is a FUL established would likely only be dispensed if the prescriber certifies that it is medically necessary and the state approves that determination. In that circumstance, the FUL would not apply and the state would use an alternate payment methodology for that drug that would recognize its cost. It is possible that a pharmacy may elect to dispense a brand name drug without such a medically necessary determination, but there is no requirement to do so under Medicaid law when generic drugs are available. We also note the pharmacy would do so knowing that it would probably lose money on that transaction. Further, under section 1903(i)(10)(B) of the Social Security Act, CMS is prohibited from providing federal funds for any amount for an innovator multiple source drug above the FULs when a generic drug could be dispensed. Accordingly, we think a pharmacy would rarely dispense a brand name drug without it being determined medically necessary and therefore not subject to the FUL.

The GAO recommendations and HHS responses are discussed below.

GAO Recommendation

The GAO recommends that CMS should expeditiously implement the PPACA-based FUL formula to better control federal reimbursement for Medicaid covered outpatient prescription drugs.

HHS Response

1

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE (GAO) DRAFT REPORT: "MEDICAID PRESCRIPTION DRUGS: CMS SHOULD IMPLEMENT REVISED FEDERAL UPPER LIMITS AND MONITOR THEIR RELATIONSHIP TO RETAIL PHARMACY ACQUISITION COSTS" (GAO-14-68)

HHS concurs. As previously noted, CMS has notified states that it intends to finalize the FULs in July 2014. This timeframe is in response to requests from the states to give them adequate time to decide on a FULs methodology, submit a state plan amendment, and make the necessary system changes to effectuate this change in payment.

GAO Recommendation

The GAO recommends that CMS should monitor the relationship between the PPACA-based FULs and the NADACs on an ongoing basis.

HHS Response

HHS concurs. CMS has looked at the historical relationship between the FULs and the NADAC as described above and will continue to do so.

2

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

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

Staff Acknowledgments

In addition to the contact named above, key contributors to this report were Rashmi Agarwal, Assistant Director; Aaron Holling; Laurie Pachter; Daniel Ries; Hemi Tewarson; and Stephen Ulrich.

Related GAO Products

Medicaid Outpatient Prescription Drugs: Estimated Changes to Federal Upper Limits Using the Formula under the Patient Protection and Affordable Care Act. GAO-11-141R. Washington, D.C.: Dec 15, 2010.

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

Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs. GAO-07-239R. Washington, D.C.: Dec 22, 2006.