

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICAID DRUG PRICING IN
STATE MAXIMUM
ALLOWABLE COST
PROGRAMS**



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**August 2013
OEI-03-11-00640**

EXECUTIVE SUMMARY: MEDICAID DRUG PRICING IN STATE MAXIMUM ALLOWABLE COST PROGRAMS

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WHY WE DID THIS STUDY

To take advantage of lower market prices for certain multiple-source drugs, States may use the Federal upper limit (FUL) and/or State Maximum Allowable Cost (MAC) programs. However, FUL amounts have often exceeded market prices, and the Affordable Care Act (ACA), P.L. 111-148, required the Centers for Medicare & Medicaid Services (CMS) to change the method it uses to calculate these amounts. Unlike the FUL program, State MAC programs give States flexibility in determining which drugs to include in the program and in setting reimbursement rates. Because generic drug use is expected to increase under ACA provisions that expand Medicaid, an aggressive MAC program may help States contain Medicaid drug costs.

HOW WE DID THIS STUDY

In January 2012, we surveyed the 45 States (including the District of Columbia) with MAC programs to identify the methods used to set MAC prices and criteria used to select covered MAC drugs. We also obtained the MAC prices and drugs covered at that time. We compared States' criteria for selecting drugs and setting prices in their MAC programs. We also calculated the aggregate percentage difference between each State's MAC prices and the FUL amounts in effect for the first quarter of 2012 (based on published prices), as well as the draft FUL amounts set by the ACA (based on average manufacturer price). Finally, we identified the State with the most aggressive MAC program and calculated the potential national savings had all States used this program.

WHAT WE FOUND

Most of the 45 States with MAC programs used acquisition cost to set MAC prices. In comparison, the pre-ACA FUL amounts were, on average, nearly double State MAC prices in January 2012, in the aggregate. However, the post-ACA FUL amounts were lower, on average, than MAC prices, in the aggregate. Although these amounts were required to take effect in October 2010, as of May 2013 CMS had not implemented them. Unlike the FUL program, State MAC programs give States flexibility in setting their coverage requirements. As a result, State MAC programs covered a wide range of drugs—significantly more than are covered under the FUL program. Lastly, we found that certain States could achieve additional cost savings by using more aggressive MAC pricing formulas and inclusion criteria.

WHAT WE RECOMMEND

We recommend that CMS complete the implementation of the post-ACA FUL amounts. We also recommend that CMS encourage States to reevaluate their MAC programs for additional cost-saving opportunities. CMS concurred with both recommendations.

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OBJECTIVES

1. To determine the pricing methodologies that State Medicaid agencies (States) use to set payment amounts for their Maximum Allowable Cost (MAC) programs.
2. To compare payment amounts under State MAC programs to Federal upper limit (FUL) amounts.
3. To determine how States select the drugs included in their MAC programs.
4. To compare MAC programs and estimate the savings had all States used one State's pricing and inclusion criteria that resulted in the lowest overall drug cost.

BACKGROUND

The FUL program was established to ensure that Medicaid takes advantage of lower market prices for certain multiple-source drugs (i.e., generic drugs and brand-name drugs for which generic alternatives are available). In addition to this federally administered program, States have the option to develop their own MAC programs. Unlike the FUL program, in which both payment amounts and inclusion criteria are set by Federal law, State MAC programs give States greater latitude in (1) selecting the drugs and (2) setting the reimbursement amounts for the drugs included in their MAC programs. MAC programs enable States to achieve additional savings by setting lower reimbursement amounts for more multiple-source drugs than are included in the FUL program.

A 2004 study showed that the expansion of existing MAC programs and the creation of new ones could contribute to cost containment nationwide.¹ The cost-savings effect from a well-developed MAC program may be even more apparent now because use of generic drugs—and spending on them—is expected to increase as a result of provisions in the Affordable Care Act (ACA), P.L. 111-148, that expand the Medicaid program.² A letter to State Governors in February 2011 from the Secretary of Health

¹ Health Care Financing Review, *Generic Drug Cost Containment in Medicaid: Lessons from Five State MAC Programs*, Spring 2004, Volume 25, Number 3.

² U.S. Pharmacist, *Trends in Generic Drug Reimbursement in Medicaid and Medicare*. Accessed at <http://www.uspharmacist.com> on January 25, 2012.

and Human Services also encouraged States to increase use of generic drugs as a way to reduce costs.³

Medicaid Reimbursement for Prescription Drugs

Medicaid, jointly funded by Federal and State governments, provides health coverage for certain low-income and medically needy people. Federal Medical Assistance Percentage (FMAP) payments are the Federal funds each State receives for its Medicaid program and are based on the State's per capita income.⁴ Individual States establish eligibility requirements, benefit packages, and payment rates for their Medicaid programs under broad Federal standards. All 50 States and the District of Columbia (referred to as States) offer prescription drug coverage as part of their Medicaid benefit packages. Medicaid expenditures for prescription drugs totaled \$28 billion in 2011.⁵

Medicaid beneficiaries typically receive covered drugs through pharmacies, which are reimbursed by State Medicaid agencies. Federal regulations require, with certain exceptions, that each State's reimbursement for a covered outpatient drug not exceed, in the aggregate, the lower of (1) the estimated acquisition cost plus a reasonable dispensing fee or (2) the provider's usual and customary charge to the public for the drug.⁶ CMS gives States flexibility in defining estimated acquisition cost, with most States basing their calculation on list prices published in national compendia.^{7, 8} For certain multiple-source drugs, States also reimburse on the basis of the FUL program and/or State MAC programs.

CMS is collecting National Average Drug Acquisition Cost (NADAC) data to develop a new reimbursement benchmark for State Medicaid agencies that is more reflective of pharmacies' acquisition costs. To

³ U.S. Department of Health and Human Services, *Sebelius Outlines State Flexibility and Federal Support Available for Medicaid—Full Letter*, February 3, 2011. Accessed at <http://www.hhs.gov> on June 11, 2012.

⁴ Pursuant to section 1905(b) of the Social Security Act (the Act), FMAPs can total between 50 and 83 percent of a State's Medicaid cost.

⁵ Medicaid expenditures were calculated using data from the Centers for Medicare & Medicaid Services' (CMS) Medicaid Budget and Expenditure System. This total does not reflect rebates collected through the Medicaid drug rebate program.

⁶ 42 CFR § 447.512.

⁷ Historically, the majority of States used average wholesale price (AWP) to set reimbursement and obtained this data from the publisher First DataBank. However, First DataBank stopped publishing AWP's as of September 2011. This has forced many States to reevaluate their AWP-based methodologies. See OIG, *Replacing Average Wholesale Price: Medicaid Drug Payment Policy* (OEI-03-11-00060), July 2011.

⁸ CMS, *Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State—Quarter Ending September 2012*. Accessed at <http://www.medicaid.gov> on January 29, 2013.

develop this benchmark, CMS will use a monthly nationwide survey to obtain pharmacy drug acquisition costs from a random sample of pharmacies.

Medicaid FUL Program

The FUL program limits Medicaid reimbursement for certain multiple-source drugs and ensures that the Federal Government acts as a prudent buyer by taking advantage of market prices for multiple-source drugs.⁹ As of January 2012, 760 drugs had been identified with FUL amounts.

Criteria for Inclusion in the FUL Program

Section 1927(e)(4) of the Act generally requires CMS to establish a FUL amount for a drug when three or more formulations of the drug are rated as therapeutically and pharmaceutically equivalent by the Food and Drug Administration (FDA). In addition, Federal regulation has required that at least three suppliers of the drug be listed in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.¹⁰ FDA publishes a list of approved prescription drugs with their therapeutic equivalents in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the Orange Book.¹¹ If FDA considers the drug to be therapeutically equivalent, it receives an “A” rating.¹²

Calculating FUL Amounts

Historically, CMS sets FUL amounts equal to 150 percent of the price published in national compendia for the least costly therapeutically equivalent product that could be purchased by pharmacists in quantities of 100 tablets or capsules, plus a reasonable dispensing fee.¹³ States are required to meet the FUL requirements only in the aggregate. In other words, a State may pay more than the FUL amount for certain products as

⁹ CMS, *Federal Upper Limits*. Accessed at <http://www.medicaid.gov> on January 15, 2013.

¹⁰ See, e.g., 42 CFR § 447.332.

¹¹ FDA, *Approved Drug Products with Therapeutic Equivalent Evaluations*. Accessed at <http://www.fda.gov> on August 15, 2012. To be therapeutically equivalent, a drug must match an innovator drug in terms of active ingredients, dosage form, route of administration, strength and/or concentration, and have the same clinical effect and safety profile as the innovator drug.

¹² If there are no known bioequivalence problems, drugs are given either an AA, AN, AO, AP, or AT code, depending on the dosage form. If there are actual or potential bioequivalence problems that have been resolved, an AB code is designated. FDA gives any drug not considered therapeutically equivalent a “B” code.

¹³ See, e.g., 42 CFR § 447.332. If the drug is not commonly available in quantities of 100, the package size commonly listed is used; in the case of liquids, the commonly listed size is used.

long as these payments are balanced out by lower payments for other products.

The most commonly used published prices in setting FULs are wholesale acquisition costs (WAC), AWP, and direct prices. National compendia, such as *RedBook*, publish these figures based on information provided by drug manufacturers. Previous Office of Inspector General (OIG) work consistently found that the published prices used to set Medicaid FUL amounts often greatly exceeded prices available in the marketplace.¹⁴ For example, an October 2012 OIG report found that FUL amounts based on published prices were more than four times higher than sampled pharmacy acquisition costs.¹⁵

Changes to FUL Amounts Under the ACA. Section 2503 of the ACA amended section 1927(e) of the Act by revising FUL amounts to be no less than 175 percent of the utilization-weighted average of the most recently reported monthly average manufacturer prices (AMPs).¹⁶ The ACA changes to the FUL amounts were required to take effect in October 2010.

State MAC Programs

In addition to the FUL program, States have the option to achieve additional savings by developing MAC programs. MAC programs operate similarly to the FUL program in that States establish maximum reimbursement amounts for certain multiple-source drugs. Unlike the FUL program, States have flexibility in determining the drugs covered under their MAC programs and the formula used to set these drugs' prices. Compared to the FUL program, MAC programs enable States to achieve additional savings by (1) setting reimbursement limits for multiple-source drugs that are not included in the FUL program and (2) using a formula that results in the MAC prices being lower than FUL amounts.

State MAC programs are designed to standardize reimbursement for chemically equivalent drugs in the same strength, dosage, and package

¹⁴ For example, see OIG, *Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices* (OEI-05-05-00240), June 2005; *Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price* (OEI-03-05-00200), June 2005; or *A Comparison of Medicaid Federal Upper Limit Amounts to Acquisition Costs, Medicare Payment Amounts, and Retail Prices* (OEI-03-08-00490), August 2009.

¹⁵ OIG, *Analyzing Changes to Medicaid Federal Upper Limit Amounts* (OEI-03-11-00650), October 2012.

¹⁶ Section 2503 of the ACA also amended section 1927(k) of the Act by revising the definition of AMP. Under the ACA provisions, the new definition of AMP is the average price paid to the manufacturer for the drug in the United States by (1) wholesalers for drugs distributed to retail community pharmacies and (2) retail community pharmacies that purchase drugs directly from the manufacturer.

size.¹⁷ The MAC price will typically apply to all brand and generic drugs for each multiple-source drug.¹⁸ Because pharmacy reimbursement is based on a single MAC price (regardless of whether a generic or brand version of a drug is dispensed), the program creates a financial incentive to substitute lower-cost generic equivalents for their brand-name counterparts.¹⁹ In general, States will not reimburse pharmacies more than a drug's MAC price. However, many States provide pharmacies the option to appeal or dispute the MAC price if it is lower than the purchase price.

Reimbursement for Drugs in FUL and State MAC Programs

The FUL and State MAC programs may contain many of the same multiple-source drugs. As a result, the Federal government and States may set different upper limits for certain multiple-source drugs. States have implemented various policies to determine the payment amount when the FUL and MAC programs conflict. For example, a State may defer to the FUL amount whenever a multiple-source drug is covered under both the FUL and MAC programs. However, a State may also determine the reimbursement for covered drugs by using the lower of the FUL or State MAC prices.

METHODOLOGY

Data Sources and Collection

In January 2012, we sent online surveys to the 51 State Medicaid pharmacy directors. We asked States to provide their prescription drug reimbursement methodologies and dispensing fees and to identify whether they had a MAC program as of January 1, 2012.²⁰ We received completed surveys from 50 States.²¹ Forty-five of the fifty responding States reported

¹⁷ For example, see *Frequently Asked Questions* on Iowa's Department of Human Services Web site. Accessed at <http://www.msliciowa.com> on January 25, 2012.

¹⁸ The State's MAC rate may not apply to the brand version of the drug if the State requires a prior authorization and "brand medically necessary" is indicated on the prescription. States may also have a preferred drug list that includes the brand version of the MAC drug. In these cases, the rate applies only to the generic version of the drug. For example, see Iowa's Department of Human Services Web site, *Frequently Asked Questions*. Accessed at <http://www.msliciowa.com> on January 25, 2012.

¹⁹ Congressional Research Service, *Prescription Drug Coverage Under Medicaid*, February 6, 2008. Accessed at <http://aging.senate.gov> on January 27, 2012.

²⁰ Based on this answer, States responded to different survey questions.

²¹ We made multiple attempts to obtain a response from Nevada; however, this State did not respond to our request. From CMS's Web site, it appears that this State does not have a MAC program. See CMS, *Medicaid Prescription Reimbursement Information by State—Quarter Ending December 2011*. Accessed at <http://www.medicaid.gov> on February 22, 2012.

that they had MAC programs. We also requested that each of the 45 States with MAC programs provide a spreadsheet listing the drugs included in its MAC program and their corresponding prices. All 45 States with MAC programs provided these data during the first quarter of 2012.

Survey for States With MAC Programs. We asked the 45 responding States with MAC programs to:

- provide the pricing benchmarks (e.g., AWP, WAC, acquisition cost) and formulas used to calculate MAC prices;
- indicate whether they had changed the formula used to set MAC prices since 2010;
- indicate whether they intended to change before the end of 2012 the formula used to set MAC prices;
- describe how they determine payment when a drug is covered under both MAC and FUL programs (e.g., use the lower of the MAC price or FUL amount, defer to the MAC price, or defer to the FUL amount); and
- provide the criteria used to determine which drugs are included in their MAC programs.

To assist States in providing the criteria, we listed common criteria that States use to select drugs covered under MAC programs and asked them to indicate all that apply and to provide a description.²² For example, a State first indicates that it uses therapeutic equivalence as a criterion and then describes that it requires a drug to have at least two therapeutically equivalent versions for it to be on the MAC list.

State Data Request. We requested that each of the 45 States provide a spreadsheet listing the MAC prices for all drugs covered under its MAC program. We requested that this spreadsheet include the drug name, dosage and form, the code used to identify the drug, and the MAC price. We also asked States to provide the date the drug was added to the MAC program, the date the MAC price was last updated, and the date the drug will be removed from the MAC program (if known).

Twenty-one of the forty-five States provided Generic Code Numbers (GCN) on their spreadsheets; 10 provided Generic Sequence Numbers

²² We reviewed States' Web sites with available information to devise a list of seven commonly used criteria for selecting MAC drugs: approval rating, availability, drug cost, drug utilization, generic availability, manufacturer supply, and therapeutic equivalence. We also provided States with an "other" option to report any inclusion criteria not on this list.

(GSN); and 1 provided National Drug Codes (NDC).²³ We “crosswalked” GSNs and NDCs to (i.e., matched them up with) their corresponding GCNs using information in First DataBank’s drug compendium. The remaining 13 States either did not provide a drug code (generally because the State considered it proprietary) or provided codes that we were unable to crosswalk to a GCN. Appendix A provides more detail about our review of these spreadsheets and our crosswalking of States’ drug codes to GCNs. Table 1 provides a summary of the survey responses and spreadsheet information received from the responding States.

Table 1: Number of States Responding to Request

Data Collected from States	Number of States
Responded to Survey	50
State Had MAC Program	45
State Did Not Have MAC Program	5
Responded with Spreadsheet of MAC Prices	45
State MAC Spreadsheet Contained GCNs or Codes That Could Be Matched With GCNs	32
State MAC Spreadsheet Did Not Contain Drug Codes or Codes Could Not Be Matched With GCNs	13

Source: OIG analysis of States’ MAC survey responses, 2012.

First DataBank Drug Compendium. Using First DataBank’s drug compendium, we obtained CMS-calculated FUL amounts based on published prices for the first quarter of 2012 (i.e., pre-ACA FULs that were in effect at this time). We also used information in the drug compendium to identify the generic drugs in CMS’s Medicaid State Drug Utilization Data file.

CMS Post-ACA FULs. We obtained the January 2012 draft FUL amounts based on the ACA methodology (i.e., ACA FULs based on AMPs) from CMS’s Web site. We also reviewed information from this site to determine whether CMS had implemented the post-ACA FUL amounts as of May 2013 and whether CMS had posted information about the implementation of AMP-based FULs.

²³ GCNs and GSNs are, respectively, five-digit and six-digit numbers that are specific to the drug’s active ingredient, route of administration, dosage form, and drug strength. These codes can be used to group pharmaceutically equivalent products together and are the same across manufacturers and package sizes. NDCs are unique 11-digit identifiers that indicate the manufacturer, product dosage form, and package size of a drug.

CMS Medicaid Drug File. We obtained the Medicaid State Drug Utilization Data (hereinafter referred to as Medicaid reimbursement data) for the first half of 2011 from CMS's Web site.²⁴ These data included reimbursement and utilization information for 46 of the 51 States.²⁵ This file also listed the total Medicaid reimbursement (ingredient costs and dispensing fees), number of prescriptions, and number of units distributed for each drug provided by NDC in each State.

Data Analysis

MAC Programs' Reimbursement Formulas and Inclusion Criteria. Using the survey responses for the 45 States with MAC programs, we determined the number of States that used each pricing benchmark (or a combination of benchmarks) in setting MAC prices. We calculated the average price difference in dispensing fees between States that used average acquisition cost (AAC) in setting MAC prices and States that did not.²⁶

We also reviewed the 45 States' survey responses to determine the criteria States used to select the drugs included in their MAC programs. We calculated the number of criteria used and determined the extent to which these criteria varied among States.

Number of Covered MAC Drugs. We calculated the total number of drugs covered by each State's MAC program and the median covered by all States. We defined the number of drugs as the number of GCN codes represented on the State's MAC list. Therefore, we included in this analysis the 32 States that either used GCNs or were States for which we could crosswalk the NDC or GSN to a GCN.²⁷ We identified the States with the most- and least-covered drugs and reviewed their MAC drug inclusion criteria.

²⁴ These data were downloaded on February 23, 2012. As of May 2012, these were the most recent quarters available.

²⁵ Medicaid reimbursement data were missing for Alabama, Arizona, Nevada, Rhode Island, and Vermont. Additionally, Kansas, Louisiana, Montana, New Jersey, South Carolina, Virginia, and Washington had data for only the first or second quarter of 2011.

²⁶ For the dispensing fee comparison, we used data from 33 States that had either 1 dispensing fee, a standard dispensing fee, or a separate dispensing fee for generic drugs.

²⁷ Thirteen States were excluded because they either did not provide drug codes or because the drug codes provided were not comparable to a GCN (i.e., the drug counts would have been different because of the drug code and not because of an actual difference in the number of covered drugs).

Comparison of MAC and FUL Amounts. We determined the percentage of drugs covered by the 32 States' MAC programs that were not covered and were covered by the pre-ACA FUL program, on average.²⁸

When a drug was covered under both programs, we calculated the aggregate percentage difference between the State's MAC prices and the pre-ACA FUL amounts (i.e., FUL amounts based on published prices), on average.²⁹ We also determined the percentage of drugs with MAC prices that were lower than the pre-ACA FUL amounts for each State and on average for all 32 States. We determined the number of States that (1) reimburse using the lower of the MAC price or FUL amount; (2) defer to the MAC price; or (3) defer to the FUL amount.

We calculated the average aggregate percentage difference between the 32 States' MAC prices and the post-ACA FUL amounts (based on AMP) for January 2012. We also determined the average number of additional drugs State MAC programs covered compared to the post-ACA FUL program. We used CMS's Web site to determine whether the agency had implemented the post-ACA FUL amounts as of May 2013. See Appendix A for additional details about the FUL portion of our analysis.

Savings Estimate. Using CMS's Medicaid reimbursement data and First DataBank's drug compendium, we identified the NDCs for generic drugs and matched these to the drug's corresponding GCN. We calculated the volume-weighted average reimbursement amount per GCN in each State.³⁰ We calculated these averages for all 46 States with available Medicaid reimbursement data in the first half of 2011, including States that did not have MAC programs.

We identified the MAC program that would result in the greatest savings by estimating expenditures had each of the 32 States' MAC programs been used by the 46 States with first-half 2011 Medicaid reimbursement

²⁸ Because FULs are set by NDC, we crosswalked the NDC to its corresponding GCN and GSN code. We then matched the FUL amounts to the State's MAC prices using the drug code type provided by the State.

²⁹ We did not include all MAC prices in this comparison. For some drugs, certain States reported multiple MAC prices for the same drug code. If the MAC price varied by more than \$0.10, we removed that drug code from this analysis. If the MAC price varied by \$0.10 or less, we used the highest price in this analysis.

³⁰ To do so, we summed each State's total expenditures for a GCN and divided that by its total utilization. We doubled the reimbursement and utilization figures for the seven States that had one quarter of Medicaid reimbursement data to account for the missing quarter. This assumes that reimbursement and utilization does not change significantly from quarter to quarter.

data.^{31, 32} To identify the MAC program that would result in the greatest savings, for each of the 32 States, we performed the following steps:

- Step 1: calculated the dollar differences between the MAC prices of one State (State A) and the volume-weighted average reimbursement amounts of another State (State B) for each drug used in State B;³³
- Step 2: multiplied each drug's dollar difference by the drug's first-half 2011 utilization in State B;³⁴
- Step 3: summed these differences to get the total amount by which spending would have changed had State B used the MAC prices set by State A (we did not include dispensing fees);³⁵
- Step 4: repeated steps 1–3 until State A's MAC prices were compared to the volume-weighted average reimbursement amounts in all remaining 45 States (i.e., the 46 States with Medicaid reimbursement data, minus State A); and
- Step 5: calculated the aggregate amount Medicaid spending would have changed had each of the 45 States used State A's MAC program.

We performed these five steps for all 32 States for which we had GCNs. This resulted in 32 spending estimates based on Medicaid reimbursement data for 46 States. We then identified which MAC program would have resulted in the greatest savings estimate (see Appendix A for more detail on this analysis). We also calculated the percentage reduction in Medicaid spending on generics in each of the 46 States had they used the MAC program with the greatest savings.

³¹ The 32 States are the States that provided GCNs or provided drug codes that we crosswalked to a GCN.

³² Although the States' MAC prices and drugs were current as of January, February, or March 2012, the most recent data we could use as the basis for our estimates were the first and second quarters of 2011.

³³ This analysis applies only to those drugs for which, for example, State A set a MAC price for a drug and State B had Medicaid utilization for that same drug. Therefore, this savings analysis takes into account not only savings resulting from lower MAC prices, but also savings resulting from a more extensive MAC list.

³⁴ For certain drugs, a State may have set more than one MAC price for one GCN. In these cases, we excluded the drug if the price varied by more than \$0.10. If the prices varied by \$0.10 or less, we used the highest MAC price for that drug in this analysis. See Appendix A for more detail.

³⁵ We subtracted the amount spent on dispensing fees from each State's total. To do so, we multiplied the State's dispensing fee by the total number of prescriptions per GCN and then subtracted this amount from that GCN's total expenditures. We obtained the State's dispensing fee amount from its survey response. If a State applied different dispensing fees for brand or generic drugs, we used the fee for generics; if a State used a tiered dispensing fees system, we used the tier's average price.

Limitations

The surveys and MAC spreadsheets were all self-reported data provided by States. We did not independently verify the accuracy of these data. All MAC prices provided by States were current at the time States provided the information (i.e., within the first quarter of 2012).

Of the 45 States with MAC programs, 8 were unable to provide drug codes that corresponded to their MAC prices and 5 provided drug codes that we were unable to link to other codes. Therefore, we did not include these 13 States' MAC prices in our determination of the State with the MAC program resulting in the overall greatest savings. This means that any of these 13 States may have had a MAC program that could produce a higher aggregate savings estimate than the 32 States included in the analysis. We also were unable to use these 13 States' data in our comparisons of MAC and FUL prices and in the calculation of the number of drugs included in each State's MAC program.

We did not verify the completeness or accuracy of CMS's FUL amounts. The post-ACA FUL amounts provided on CMS's Web site are draft amounts that have not been used as the basis for Medicaid reimbursement. We also did not verify the accuracy of the FUL amounts obtained from First DataBank's Web site.

The savings estimates reflect the amount by which a State could reduce spending on generic drugs had it used the prices for drugs included in another State's MAC program; this estimate does not take into account the effect that replacing a MAC program may have on the State's prices for all drugs. In addition, the first and second quarter of 2011 Medicaid reimbursement data we obtained from CMS's Web site did not include data for 5 of the 51 States. Our savings estimates would have been different had we been able to include data from these States. Lastly, seven States had reimbursement and utilization data for just one of the two quarters. We doubled the reimbursement and utilization in these States, which assumes that these figures would not change significantly from quarter to quarter.

Standards

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

FINDINGS

Most States with MAC programs used acquisition cost as the basis for setting MAC prices

Of the 45 States with MAC programs, 41 provided the pricing benchmark used as the basis to set these prices.³⁶ Twenty-nine of the forty-one States (71 percent) reported using pharmacy acquisition cost as either the sole basis for setting MAC prices or in conjunction with other benchmarks. Specifically, 14 of the 29 States used only acquisition cost, and the other 15 used a combination of acquisition cost and WAC, AWP and/or AMP.^{37, 38} See Table 2 for the benchmarks all States used as the basis for setting MAC prices and Appendix B for individual States' benchmarks.

Table 2: Drug Pricing Benchmarks States Use To Set MAC Prices

Benchmark(s) Used To Set MAC Prices	Number of States
<i>Formula includes acquisition cost</i>	
Acquisition cost	14
Acquisition cost and WAC	10
Acquisition cost, WAC, and AWP	4
Acquisition cost, WAC, AWP, and AMP	1
<i>Formula does not include acquisition cost</i>	
WAC and AWP	5
WAC	5
AWP	2
Total Number of States Providing Benchmarks	41
<i>State did not provide benchmark</i>	
No specific benchmark used in MAC formula	1
Benchmark used in MAC formula was proprietary	3

Source: OIG analysis of State MAC surveys, 2012.

Note: Four States that provided benchmarks also reported using additional benchmarks that are not shown in this table.

³⁶ Three States reported that this information is proprietary, and one State reported that it did not use a specific benchmark.

³⁷ Two States reported that they also used other State MAC lists as a reference in setting their MAC prices.

³⁸ States that used a combination of benchmarks may, for example, apply a different formula based on WAC and acquisition cost to the same drug and select the lowest resulting MAC price. However, many States reported that the exact formula was proprietary and did not explain how they used multiple benchmarks to set MAC prices.

The 29 States reported obtaining acquisition cost data from sources such as pharmacy surveys and invoices, wholesaler and retailer data purchased by the State's contractor, or through a proprietary database. A small number of States specifically mentioned that they apply a percentage markup to the acquisition cost to set a MAC price. For example, one State calculated MAC prices using the AAC plus 120 percent, whereas another State set it at 150 percent of the lowest acquisition cost. Many States could not provide a formula either because it was considered proprietary or because they do not use a specific formula (e.g., they calculate on a case-by-case basis, they use a multi-step pricing factor calculation, or they vary the price in response to market trends).

In addition to the MAC price, the total Medicaid payment for a drug includes a dispensing fee. Among 33 MAC States, dispensing fees ranged from \$1.75 to \$10.64 per prescription.³⁹ On average, those States using acquisition cost to set MAC prices, either solely or in conjunction with another pricing benchmark, set dispensing fees that were \$0.44 higher than States not using acquisition cost (\$4.40 compared to \$3.96). See Appendix B for a list of States' dispensing fees.

Aggregate pre-ACA FUL amounts were higher than State MAC prices, on average; however, the post-ACA FUL amounts were lower

Effective October 2010, section 2503 of the ACA required CMS to change the method it uses to calculate FUL amounts. CMS has taken steps to implement the post-ACA FUL amount by calculating the new amounts and issuing draft FUL amounts based on AMPs for review and comment.⁴⁰ However, as of May 2013, CMS had yet to implement these changes and continues to base FUL amounts on 150 percent of the lowest published price.⁴¹ Prior OIG reports have consistently found that these published prices often exceed prices available in the marketplace.

In addition to issuing the draft post-ACA FUL amounts, which represent monthly prices, CMS has also made available draft 3-month rolling averages of the post-ACA FUL amounts. CMS developed these averages in response to comments that the post-ACA FULs fluctuate and, as a result, could create problems for pharmacies because they would be unable to predict State reimbursement rates. According to CMS's Web

³⁹ These are the States that provided a single, standard, or generic dispensing fee.

⁴⁰ CMS, *Draft Affordable Care Act Federal Upper Limits*. Accessed at <http://www.medicaid.gov> on April 17, 2013.

⁴¹ Ibid.

site, once the draft post-ACA FUL amounts and the draft 3-month rolling average FUL amounts are finalized, States can use either of these to develop a pharmacy reimbursement methodology that will allow their pharmacy payments to remain within the FUL in the aggregate (depending on the approved state plan).⁴²

On average, pre-ACA FUL amounts were nearly double State MAC prices, in the aggregate

The pre-ACA FUL amounts in effect for January 2012 were an average of 1.96 times greater, in the aggregate, than the MAC prices set by the 32 States.⁴³ In fact, all States except Hawaii had lower aggregate MAC prices than pre-ACA FUL amounts (Hawaii’s MAC prices were 2.3 times greater than pre-ACA FUL amounts). See Table 3 for the comparisons between State MAC prices and pre-ACA FUL amounts and Appendix C for individual State comparisons.

Table 3: Comparison of Pre-ACA FUL Amounts and MAC Prices

Comparison of Pre-ACA FUL and MAC Prices*	Number of States
Aggregate FUL amount less than aggregate MAC prices	1
Aggregate FUL amount between 1 and 1.5 times higher than aggregate MAC prices	5
Aggregate FUL amount between 1.51 and 2.0 times higher than aggregate MAC prices	8
Aggregate FUL amount between 2.01 and 2.5 times higher than aggregate MAC prices	15
Aggregate FUL amount between 2.51 and 3.0 times higher than aggregate MAC prices	3
Total Number of States	32
Average Amount Aggregate FUL Is Greater Than Aggregate MAC	1.96 times
Median Amount Aggregate FUL Is Greater Than Aggregate MAC	2.11 times

Source: OIG analysis of State MAC prices and pre-ACA FUL amounts, 2012.

* These percentages exclude certain drugs that had multiple MAC prices for each GCN within a State.

Overall, States set MAC prices that were lower than the pre-ACA FUL amounts for an average of 85 percent of the drugs covered under both programs. Twenty-eight of the thirty-two States had set MAC prices that were lower than pre-ACA FUL amounts for at least 75 percent of their covered drugs. For example, one State set MAC prices lower than the pre-ACA FUL amounts for 612 of the 613 drugs covered under both programs.

⁴² CMS, *Draft Affordable Care Act Federal Upper Limits*. Accessed at <http://www.medicaid.gov> on April 17, 2013.

⁴³ This comparison does not include dispensing fees.

Hawaii was the only State in which the majority of its covered drugs (90 percent) had higher MAC prices than pre-ACA FUL amounts. However, Hawaii was also the only State reporting that it would use the FUL amount for drugs covered under both programs. The majority of the States (21 of 32) instead reported that they defer payment to the lower price (typically the MAC price). An additional seven States reported that they always defer to the MAC price.

On average, post-ACA FUL amounts were 22 percent lower than State MAC prices, in the aggregate

Had the post-ACA FUL amounts been implemented in January 2012 (i.e., FUL amounts based on AMP), the aggregate post-ACA FUL amounts would have been 22 percent lower than the 32 States’ aggregate MAC prices, on average.⁴⁴ The post-ACA FUL amounts were lower than aggregate MAC prices in all but two States. Among the 30 States in which post-ACA FUL amounts were lower, 17 set MAC prices that were within 20 percent of the post-ACA FUL amounts. See Table 4 for the comparisons between post-ACA FULs and MAC prices and Appendix C for individual State comparisons.

Table 4: Comparison of Post-ACA FUL Amounts and MAC Prices

Percentage Comparison of Post-ACA FUL and MAC Prices*	Number of States
Aggregate post-ACA FUL amount is higher than aggregate MAC prices	2
Aggregate post-ACA FUL amount is 0.1%–10% less than aggregate MAC prices	8
Aggregate post-ACA FUL amount is 10.1%–20% less than aggregate MAC prices	9
Aggregate post-ACA FUL amount is 20.1%–30% less than aggregate MAC prices	3
Aggregate post-ACA FUL amount is 30.1%–40% less than aggregate MAC prices	4
Aggregate post-ACA FUL amount is 40.1%–50% less than aggregate MAC prices	4
Aggregate post-ACA FUL amount is over 50.1% less than aggregate MAC prices	2
Total Number of States	32
Average Percentage Aggregate Post-ACA FUL Is Less Than Aggregate MAC	22 percent
Median Percentage Aggregate Post-ACA FUL Is Less Than Aggregate MAC	15 percent

Source: OIG analysis of State MAC prices and post-ACA FUL amounts, 2012.

* These percentages exclude certain drugs that had multiple MAC prices for each GCN within a State.

⁴⁴ This comparison does not include dispensing fees.

States exercised their flexibility in setting varying MAC coverage criteria, which resulted in a wide number of covered drugs

The 45 States with MAC programs used a mixture of criteria with varying requirements when selecting covered drugs.⁴⁵ In fact, three of these States reported not using any of the criteria we had specified on the survey when determining what drugs are included in the MAC program.⁴⁶ Most States (32) required a specific number of manufacturers to supply the drug for it to be included in the MAC program, with many of these States (23 of the 32) requiring 1 or 2 manufacturers.⁴⁷ Additionally, 25 of the 29 States with criteria for the number of generic versions required at least 1 or 2 versions.⁴⁸

States may have also set inclusion requirements based on one or more of the following criteria for the drug: (1) FDA approval rating (e.g., A rated, AB rated), (2) number of therapeutically equivalent versions (e.g., two versions, three versions), (3) availability to pharmacies (e.g., excludes drugs with shortages), and (4) utilization (e.g., number of claims submitted per quarter). See Table D-1 in Appendix D for individual State details.

The Number of Drugs Included in States' MAC Programs Ranged From 494 to 5,355. In January 2012, the 32 States with GCN codes covered between 494 drugs in Montana to 5,355 drugs in Massachusetts (median of 1,675 drugs; see Figure 1 and Table D-2 in Appendix D). Montana reported that it would include A-rated therapeutically equivalent drugs with at least three rebate-eligible manufacturers (e.g., two generic and one brand manufacturer) in its MAC program.⁴⁹ The criteria set by Massachusetts, the State with the most drugs in its MAC program, was not

⁴⁵ Additionally, three States specifically excluded certain drug groups, such as HIV drugs, vaccines, or blood clotting factors from the MAC program, regardless of whether the drug met the States' criteria.

⁴⁶ Instead, one State required that the drug have an active, rebateable NDC; one State's criteria depended on and varied as to whether the drug was new to the MAC program or already included; and one State did not have criteria for selecting drugs included in its MAC program.

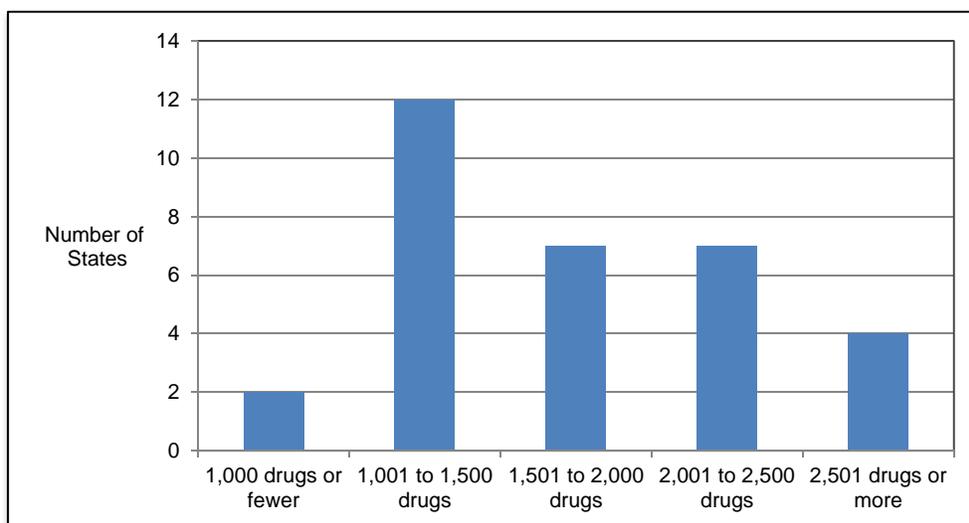
⁴⁷ Some of these States specified that these manufacturers must be rebate eligible or generic manufacturers. For example, a State requiring two rebate-eligible manufacturers specified that it could be one brand and one generic manufacturer or no brand manufacturer and two generic manufacturers.

⁴⁸ These criteria may overlap somewhat with the manufacturer supply criteria. For example, 10 States did not require a specific number of generic versions but did require a specific number of drug manufacturers.

⁴⁹ In addition, Montana reported that its contractor monitors drug shortages to ensure that the MAC drug is readily available. Montana also assesses the net cost of the MAC price to determine if its use is financially advantageous.

as restrictive and required only that the drug have at least four claims in the prior 90 days.

Figure 1. Number of MAC Drugs Covered in the 32 States



Source: OIG analysis of State MAC spreadsheets, 2012.

State MAC programs covered significantly more drugs than the FUL program

Unlike the FUL program, which selects covered drugs on the basis of Federal law and regulation, States are afforded flexibility in selecting which drugs to cover under their MAC programs. This enables States to cover substantially more drugs than both the pre- and post-ACA FUL programs.

On average, 60 percent of the drugs covered by 32 States' MAC programs were not covered by the pre-ACA FUL program

All of these 32 States' MAC programs included drugs covered and drugs not covered under the pre-ACA FUL program in January 2012 (i.e., the FUL amounts in effect that were based on published prices).⁵⁰ On average, the majority (60 percent) of drugs that States included in their MAC programs were not covered under the pre-ACA FUL program as of January 2012. States' MAC programs covered an additional 203 to 4,607 drugs that were not included in the pre-ACA FUL program. See Table 5 for the numbers of States and their percentages and average numbers of MAC drugs not covered under the pre-ACA FUL program.

⁵⁰ The pre-ACA FUL program covered 760 drugs in January 2012.

Massachusetts' MAC program covered the highest percentage of drugs not included in the pre-ACA FUL program (86 percent). Conversely, Ohio's MAC program, which included 926 drugs, covered the lowest percentage (36 percent) of drugs not included in the pre-ACA FUL program.

Table 5: Percentage of States' MAC Drugs Not Covered Under the Pre-ACA FUL Program

Number of Drugs in MAC Program	Number of States	Average Number of Drugs Not Covered Under Pre-ACA FUL	Average Percentage of Drugs Not Covered Under Pre-ACA FUL
1,000 drugs or fewer	2	268	39%
1,001 to 1,500 drugs	12	724	53%
1,501 to 2,000 drugs	7	1,021	59%
2,001 to 2,500 drugs	7	1,430	66%
2,501 drugs or more	4	3,046	79%

Source: OIG analysis of State MAC prices and pre-ACA FUL amounts, 2012.

On average, 53 percent of the drugs covered by States' MAC programs were not covered by the post-ACA FUL program

Although the post-ACA FUL amounts were less than the States' MAC prices for the majority of the drugs covered under both programs, States still covered a significantly higher number of drugs in their MAC programs. On average, States set MAC prices for 1,089 more drugs than were covered under the post-ACA FUL program.⁵¹ This means that States would need to continue to rely on their MAC program to set prices for these drugs. See Table 6 for the percentage and average number of MAC drugs not covered under the post-ACA FUL program.

Table 6: Percentage of States' MAC Drugs Not Covered Under the Post-ACA FUL Program

Number of Drugs in MAC Program	Number of States	Average Number of Drugs Not Covered Under Post-ACA FUL	Average Percentage of Drugs Not Covered Under Post-ACA FUL
1,000 drugs or fewer	2	244	33%
1,001 to 1,500 drugs	12	616	46%
1,501 to 2,000 drugs	7	897	52%
2,001 to 2,500 drugs	7	1,290	60%
2,501 drugs or more	4	2,912	75%

Source: OIG analysis of State MAC prices and post-ACA FUL amounts, 2012.

⁵¹ The post-ACA FUL program covered 924 drugs in January 2012.

States may achieve additional cost savings by using different MAC pricing formulas and inclusion criteria

Until the post-ACA FUL amounts are implemented, certain States could significantly reduce drug expenditures by changing to the structure of their MAC programs. Once the post-ACA FUL amounts are implemented, States can still achieve significant savings because they have the opportunity to cover a significantly larger number of drugs in the MAC programs than in the FUL program.

We identified Wyoming's MAC program as the one that could produce the greatest savings had all other States considered using it as a model.^{52, 53} We found that 39 of 45 States would have saved \$483 million in the first half of 2011 (this estimate excludes dispensing fees) had they used Wyoming's MAC program.^{54, 55} Wyoming set MAC prices for its 1,592 drugs by comparing and using prices on the basis of (1) acquisition cost plus a markup, (2) WAC minus a percentage, (3) AWP minus a percentage, or (4) AMP plus a markup.

Fourteen States could have reduced spending on generic drugs by more than 20 percent had they used Wyoming's MAC program

We estimated that using Wyoming's MAC program (excluding dispensing fees) would have resulted in the greatest percentage reduction in Medicaid generic-drug spending for Alaska. Had Alaska reimbursed for generic drugs using Wyoming's MAC prices, it would have reduced expenditures for generic drugs from \$43 million to \$22 million (50 percent decrease) in the first half of 2011. Alaska's higher expenditures are most likely caused by its lack of a MAC program in the first half of 2011 and its use of AWPs as the basis for reimbursement.⁵⁶ See Table 7 for the percentage reduction

⁵² This savings estimate is based on the prices for the drugs included in Wyoming's MAC program.

⁵³ We were able to use only the data from the 32 States with MAC programs that provided GCNs or provided drug codes we crosswalked to a GCN. This means that the 13 other States may or may not have had a more aggressive MAC program.

⁵⁴ Although Wyoming's MAC program resulted in the greatest aggregate savings, six States would have spent an additional \$18 million on generic drugs had they used Wyoming's MAC program. All six States used acquisition cost data (among other benchmarks) in setting reimbursement prices. In fact, one of these States had eliminated its MAC programs because, according to the State, reimbursement based on actual acquisition cost was lower than previous MAC prices.

⁵⁵ We also determined which State had the most advantageous combination of MAC pricing and dispensing fees. Including dispensing fees, Michigan's reimbursement formula would have resulted in the greatest savings. Michigan's standard dispensing fee per prescription was \$2.75, compared to \$5.00 in Wyoming.

⁵⁶ Alaska implemented a MAC program in September 2011.

in generic-drug spending if States had applied Wyoming’s MAC program in the first half of 2011.

Table 7: Percentage Reduction or Increase in State Spending on Generic Drugs by Using Wyoming’s MAC Program

Range of Reduction or Increase	Number of States
Spending reduction between 40.01% and 50%	2
Spending reduction between 30.01% and 40%	3
Spending reduction between 20.01% and 30%	9
Spending reduction between 10.01% and 20%	18
Spending reduction between 0.01% and 10%	7
Spending Increase	6
Total Number of States	45

Source: OIG analysis of State MAC data, 2012.

CONCLUSION AND RECOMMENDATIONS

As a result of expansions set forth in the ACA, it is estimated that an additional 10 million people will enroll in Medicaid by 2016 and that use of and spending on generic drugs will increase. In preparation for this increase in Medicaid use and expenditures, it is in the States' best financial interest to reevaluate and for CMS to implement cost-containment strategies. Our findings demonstrate the significant value MAC programs have in containing Medicaid drug costs. This is because States can develop MAC programs that: (1) set drug prices lower than FUL amounts and (2) cover substantially more drugs than the FUL program does.

To maximize Medicaid drug cost-containment strategies, we recommend that CMS:

Complete Implementation of Post-ACA AMP-Based FUL Amounts

Consistent with previous OIG work, our findings show that FUL amounts based on published prices greatly exceed other price points, in this case the State MAC prices. Although the post-ACA FUL amounts were to take effect in October 2010, as of May 2013, CMS had yet to implement these amounts. This means that FUL amounts are still based on prices that result in inflated payments for many multiple-source drugs. Our findings highlight the necessity for States to use a MAC program as a tool for containing Medicaid drug costs, especially when the pre-ACA FULs remain in effect.

Although we found that, on average, post-ACA FUL amounts were lower than the MAC prices in the aggregate, this does not necessarily mean that the post-ACA FUL amounts will reimburse States below their acquisition costs. Many of the States that based MAC pricing on acquisition cost did not reimburse at acquisition cost but applied a markup to set the price. In addition, a prior OIG report had found that sampled pharmacy acquisition costs are still lower than the post-ACA FUL amounts, in the aggregate.⁵⁷

CMS is also developing price points for States to use to ensure that Medicaid payment amounts do not over- or underestimate the costs pharmacies pay for drugs. For example, States may compare their MAC prices to the acquisition costs collected through CMS's NADAC surveys (published in draft form as of May 2013). In addition, CMS is developing 3-month rolling average post-ACA FUL amounts that States can use in place of the monthly post-ACA FUL amounts we used in our analysis.

⁵⁷ OIG, *Analyzing Changes to Medicaid Federal Upper Limit Amounts* (OEI-03-11-00650), October 2012.

Once the rolling average FUL amounts are finalized, States may use these to develop a pharmacy reimbursement methodology that will allow their pharmacy payments to remain within the post-ACA FUL, in the aggregate (pending CMS review and approval of their respective State Medicaid plans).

Encourage States To Reevaluate Their MAC Programs To Identify Additional Cost-Saving Opportunities

States may also have the opportunity to strengthen the cost-effectiveness of their MAC programs. States varied in the structure and aggressiveness of their MAC programs, giving certain States the potential to further reduce their drug spending if they model their MAC program after that of another State. This can be achieved through changes to the State's inclusion criteria and/or to the State's methodology to set the MAC prices.

In addition, the flexibility States have when determining covered MAC drugs enabled them to cover significantly more drugs than the pre-ACA FUL program. This allowed States to further optimize their cost containment by limiting reimbursement for a greater number of drugs than the FUL program does. The need for a MAC program to maximize drug cost containment will remain even after the post-ACA FULs are implemented. The latitude that States have to develop MAC criteria that are less restrictive than those of the FUL program allows States to continue to set reimbursement limits on considerably more multiple-source drugs, in addition to still setting MAC prices lower than FULs for a number of drugs covered under both programs.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with both recommendations. In response to our first recommendation, CMS stated that it plans to finalize the post-ACA AMP-based FUL amounts in the near future. CMS also stated that it plans to release an informational bulletin that encourages States to reevaluate their MAC programs for cost-saving opportunities in the near future.

We did not make any changes to the report based on CMS's comments. The full text of CMS's comments is provided in Appendix E.

APPENDIX A

Methodology Used To Compare State Maximum Allowable Cost (MAC) Programs

Review of State MAC Lists. Each of the 45 States with MAC programs provided a spreadsheet of MAC prices. We reviewed each MAC spreadsheet and kept prices that were current as of January 1, 2012. To do so, we removed any MAC prices for which the State provided an end date of December 31, 2011, or earlier. We also verified that the MAC spreadsheets did not contain duplicate drug prices and followed up with States for clarification when necessary.

All States did not use the same drug code to identify and set MAC prices for drugs. Eight of the forty-five States reported that drug codes were proprietary information and did not provide any drug codes. Among the 37 States that provided drug codes:

- 21 used Generic Code Numbers (GCN),
- 10 used Generic Sequence Numbers (GSN),
- 4 used Group Product Identifiers (GPI),
- 1 used Generic Formulation Codes (GFC), and
- 1 used National Drug Codes (NDC).⁵⁸

The GCN, GSN, GPI, and GFC are similar in that they are used to group pharmaceutically equivalent drugs marketed by multiple manufacturers and are specific to the active ingredient, route of administration, dosage form and drug strength. These drug codes vary in digit length and/or publishing company.

Crosswalking Drug Codes. Using information in First DataBank's National Drug Data File, we matched the GSNs, GCNs, and NDCs to create a database crosswalking all three types of drugs codes. Because NDCs are manufacturer-specific and GCNs are not, one GCN often matched to multiple NDCs. In general, most GSNs had one-to-one matches to GCNs. There were a few instances in which GSN-to-GCN crosswalking resulted in a slightly lower count of covered drug codes. For example, 1 State covered 2,082 GSN codes, but when crosswalked it translated to 2,080 GCN codes. We were unable to crosswalk State spreadsheets with GFC, GPI, or no drug codes. As a result, portions of the

⁵⁸ One State used GCN codes for most of its drugs, but set MAC prices by NDC for certain drug types. In this count, we have classified this State as using GCNs.

analysis involving MAC price comparisons (i.e., MAC and FUL price comparisons and State savings estimates) include 32 States.

Comparison of MAC and FUL Amounts. We obtained the pre-Affordable Care Act (ACA) FUL amounts from First DataBank for the first quarter of 2012, which are listed by NDC. We matched the NDC to the corresponding GCN and GSN (this eliminated the need to crosswalk State MAC data for this analysis). Depending on whether the State used a GCN or GSN, we matched the FUL amounts to the 32 States' MAC data and identified the drugs covered under both programs.

Sixteen of the thirty-two States had multiple MAC prices for certain drugs. This may have occurred when, for example, the State set a different price for each package size of the drug. If the MAC price variation was \$0.10 or less, we selected the highest MAC price for this comparison. However, if the MAC price varied by more than \$0.10 for the same drug code, we removed that code from this portion of the analysis. Less than 3 percent of drug codes were removed for most (12) of the 16 States. However, the remaining 4 States had between 6 and 28 percent of their drug codes removed for the following analyses involving State MAC drug prices.

We calculated the percentage difference between each State's aggregate MAC price and the aggregate pre-ACA FUL amount (based on published prices), on average.⁵⁹ We determined the percentage of drugs with MAC prices that were lower than the pre-ACA FUL amounts for each State and on average for all States. We also reviewed the 32 States' survey responses and determined the number of States that, when the drug was covered under both programs, (1) reimburse using the lower of the MAC price or FUL amount; (2) defer to the MAC price; or (3) defer to the FUL amount.

Finally, we calculated the percentage difference between each State's aggregate MAC price and the aggregate post-ACA FUL amount for January 2012 (based on average manufacturer price). We also determined the average number of additional drugs State MAC programs covered than the post-ACA FUL program.

Savings Estimate. We had to use the same drug code to make MAC prices comparable among States. This means that we could compare only the MAC programs among the 21 States that provided GCNs and the 11 States where we could crosswalk the GSN or NDC to a GCN. We applied the same method described above (i.e., \$0.10 method) to select or remove the MAC price when the State set more than one price for a drug code.

⁵⁹ We did not include dispensing fees.

We substituted MAC prices used in each of these 32 States and determined the difference in reimbursement had each State used another State's MAC program. For example, if State A set a MAC price for GCN 00001, we calculated the difference between State A's MAC price and State B's average volume-weighted reimbursement amount and then multiplied this difference by State B's total utilization for GCN 00001. We completed this comparison for all of State B's drugs that were also covered by State A's MAC program. We summed the total estimated difference in State B's Medicaid spending had it used State A's MAC program. We continued our comparison of State A's MAC prices to the average volume-weighted reimbursement amounts in State C, State D, and so forth until State A's MAC prices were compared to each State with data in CMS's Medicaid reimbursement and utilization file for the first and second quarters of 2011.

We used the first two quarters of 2011 from the Medicaid reimbursement file to calculate States' average volume-weighted reimbursement amounts. By using these quarters and the January 2012 MAC prices to estimate savings, we assumed that spending and utilization would not change significantly from month to month. This file did not contain data for all States; we could compute average volume-weighted reimbursement amounts for only 46 States.⁶⁰

⁶⁰ This also contained only one-quarter of data for seven States. We doubled the reimbursement and utilization in these States to estimate total first half of 2011 amounts.

APPENDIX B

Table B-1: Dispensing Fees and Benchmarks Used As the Basis For Setting State Maximum Allowable Cost (MAC) Prices

State	State Benchmark Used For MAC Prices	Dispensing Fee in First Quarter 2012*
Alabama	WAC, ¹ AAC ²	\$10.64
Alaska	AWP, ³ WAC	Multiple dispensing fees ranging from \$12.12 to \$26.74 for in-state pharmacies
Arkansas	AAC	\$5.51 for MAC generics
Colorado	AAC	\$4.00 for retail pharmacies; \$1.89 for institutional pharmacies
Connecticut	AWP	\$2.00
District of Columbia	WAC	\$4.50
Delaware	AWP, WAC	\$3.65
Florida	Proprietary	\$3.73
Georgia	AWP, WAC, AAC	\$4.63 for profit pharmacies; \$4.33 for nonprofit pharmacies
Hawaii	AWP	\$4.67 for pharmacies
Illinois	WAC, AAC	\$4.60 for generics
Indiana	AAC	\$3.00 standard fee
Iowa	AAC	\$6.20
Kansas	WAC	\$3.40
Kentucky	WAC, AAC	\$5.00 for generics
Louisiana	AAC	\$5.77 maximum fee
Maine	AAC	\$3.35 for retail pharmacies; \$1.00 for mail-order pharmacies
Maryland	AAC	\$3.51
Massachusetts	AWP, WAC	\$3.00
Michigan	WAC, AAC	\$2.75
Minnesota	WAC, AAC ⁴	\$3.65
Missouri	AAC	Multiple dispensing fees ranging from \$9.66 to \$13.66
Montana	AAC	Multiple dispensing fees ranging from \$2.00 to \$6.40
Nebraska	N/A ⁵	Multiple dispensing fees ranging from \$3.25 to \$5.00

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Table B-1: Dispensing Fees and Benchmarks Used As the Basis For Setting State MAC Prices

State	State Benchmark Used For MAC Prices	Dispensing Fee in First Quarter 2012*
New Hampshire	WAC, AAC	\$1.75
New Jersey	AAC	\$3.73
New Mexico	WAC	Multiple dispensing fees ranging from \$2.50 to \$3.65
New York	WAC, AAC	\$3.50
North Carolina	AAC	\$5.60 for generics
North Dakota	AAC	\$5.60 for generics
Ohio	WAC, AAC	\$1.80
Oklahoma	Proprietary	\$4.02
Pennsylvania	AAC	\$4.00
Rhode Island	AWP, WAC	\$3.40 for retail pharmacies
South Carolina	WAC, AAC	\$3.00
South Dakota	Proprietary	\$4.30
Tennessee	AWP, WAC, AAC	\$2.50 for generics
Texas	AWP, WAC	\$6.50
Utah	AWP, WAC, AAC ⁶	\$1.00 for over-the-counter drugs; \$3.90 for urban pharmacies; \$4.40 for rural pharmacies
Vermont	AWP, WAC, AAC	\$4.75 for in-state pharmacies
Virginia	WAC	\$3.75
Washington	AAC	Multiple dispensing fees ranging from \$4.24 to \$5.25
West Virginia	WAC, AAC	\$5.30 for generics
Wisconsin	WAC	\$3.94 for generics
Wyoming	AWP, AMP, ⁷ WAC, AAC	\$5.00

Source: Office of Inspector General analysis of State MAC survey responses, 2012.

* States may have additional dispensing fees. We excluded fees that are specific for brand-name drugs, compounded drugs, intravenous solutions, out-of-State pharmacies, 340B entities, and long-term-care/nursing home facilities.

¹ Wholesale acquisition cost.

² Average acquisition cost.

³ Average wholesale price.

⁴ Minnesota also uses other State MAC lists to assist in setting MAC prices.

⁵ Not applicable. Nebraska does not have a standard formula to set MAC prices.

⁶ Utah also uses other State MAC lists to assist in setting MAC prices.

⁷ Average manufacturer price.

APPENDIX C

Table C-1: State Maximum Allowable Cost (MAC) Prices Compared to Federal Upper Limit (FUL) Amounts

State	Percentage of MAC Drugs with Prices Less Than Pre-ACA FUL*	Percentage Difference Between Pre-ACA FUL Amount and MAC Prices	Percentage of MAC Drugs with Prices Less Than Post-ACA FUL**	Percentage Difference Between Post-ACA FUL Amount and MAC Prices
Alabama	88.1%	146.9%	59.7%	-2.5%
Arkansas	80.5%	67.4%	13.0%	-32.8%
Colorado	58.9%	15.5%	7.8%	-40.1%
District of Columbia	80.4%	69.9%	20.9%	-35.0%
Hawaii	10.0%	-55.7%	3.3%	-76.0%
Iowa	99.8%	184.3%	40.8%	-13.2%
Illinois	91.6%	137.9%	42.4%	-5.7%
Indiana	88.4%	115.4%	43.5%	-10.1%
Kansas	95.1%	111.8%	30.1%	-17.7%
Louisiana	81.3%	71.2%	12.4%	-49.2%
Massachusetts	76.1%	13.8%	12.4%	-45.5%
Maryland	86.6%	132.4%	41.8%	2.2%
Michigan	94.7%	136.1%	45.3%	0.3%
Minnesota	94.3%	111.0%	35.9%	-7.2%
Missouri	88.7%	122.1%	35.1%	-21.3%
Montana	94.2%	180.1%	33.2%	-10.8%
North Carolina	84.3%	90.4%	21.6%	-31.9%
North Dakota	82.3%	84.5%	26.6%	-9.3%
Nebraska	88.3%	70.4%	25.4%	-20.4%
New Jersey	90.2%	127.9%	38.5%	-15.3%
New Mexico	62.4%	1.4%	8.5%	-48.5%
New York	94.0%	139.3%	40.6%	-6.1%

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Table C-1: State MAC Prices Compared to FUL Amounts (Continued)

State	Percentage of MAC Drugs with Prices Less Than Pre-ACA FUL*	Percentage Difference Between Pre-ACA FUL Amount and MAC Prices	Percentage of MAC Drugs with Prices Less Than Post-ACA FUL **	Percentage Difference Between Post-ACA FUL Amount and MAC Prices
Ohio	97.0%	69.9%	24.9%	-29.2%
Oklahoma	69.2%	91.9%	26.4%	-3.3%
Pennsylvania	88.7%	121.6%	35.1%	-19.5%
South Dakota	98.5%	111.1%	25.9%	-14.1%
Texas	94.2%	46.7%	20.2%	-32.6%
Utah	92.1%	18.3%	12.0%	-55.8%
Washington	88.7%	128.1%	37.7%	-6.5%
Wisconsin	88.9%	126.5%	40.2%	-13.8%
West Virginia	93.3%	126.3%	40.5%	-10.8%
Wyoming	96.6%	165.3%	46.0%	-5.8%

Source: Office of Inspector General analysis of State survey responses and the Centers for Medicare & Medicaid Services FUL amounts, 2012.

* FUL amounts based on published prices compared to MAC prices.

** FUL amounts set by the Affordable Care Act (ACA), which are based on average manufacturer prices, compared to MAC prices.

APPENDIX D

Criteria States Use To Select Drugs Included in State Maximum Allowable Cost (MAC) Programs

We asked each State about the criteria used to determine the drugs included in its MAC program. We provided States with a list of criteria, along with examples:

- approval rating (e.g., Orange Book or Food and Drug Administration (FDA) rating);
- therapeutic equivalence (TE) (e.g., must have at least two TE versions of a drug);
- generic availability (e.g., must be at least two generic versions);
- manufacturer supply (e.g., must be supplied by at least three manufacturers);
- pharmacy availability (e.g., must be available in at least three pharmacies);
- drug cost (e.g., drug price increased more than 5 percent in the last quarter);
- utilization (e.g., at least 500 beneficiaries have prescriptions for a drug); and
- any other criteria not listed above.

Table D-1 depicts the criteria response for each State as well as a short descriptor of the State's applicable criteria. Table D-2 provides the number of drug codes covered under each State's MAC program. It also includes the number of covered drug codes after crosswalking to a Generic Code Number (GCN).

Table D-1: Criteria States Use To Select Drugs Included in MAC Programs

State	Criteria					
	Approval Rating	Therapeutic Equivalence (TE)	Minimum Number of Available Generics	Manufacturer Supply	Pharmacy Availability	Drug Cost
Alabama			One generic version			
Alaska	A-rated generics ¹	Two TE versions	Two generic versions	Two manufacturers	On market	Significant cost difference (thresholds are proprietary)
Arkansas	AB rated; case-by-case evaluation		Two generic versions	Two manufacturers	Available by multiple wholesalers and pharmacies	
Colorado	A rated			Two manufacturers		
Connecticut	AB rated		Two generic versions	Two manufacturers		
District of Columbia ²	AB rated	Number of TE versions not specified	Three generic versions		Three or more pharmacies submit claims in prior quarter	
Delaware ³	A rated	Three TE versions	Number of generic versions not provided	Three rebate-eligible manufacturers		
Florida			Number of generic versions not provided			
Georgia	A rated	All versions are TE	Two generic versions	Two rebate-eligible generic manufacturers	Readily available	

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Table D-1: Criteria States Use To Select Drugs Included in MAC Programs (Continued)

State	Criteria					
	Approval Rating	Therapeutic Equivalence	Minimum Number of Available Generics	Manufacturer Supply	Pharmacy Availability	Drug Cost
Illinois			One generic version	Two manufacturers		
Indiana	A rated	At least one TE version	One generic version	One generic manufacturer		
Iowa	A rated	At least one TE version	One generic version	Two manufacturers		
Kansas	A rated	Number of TE versions not specified	One generic version		Case-by-case if availability is an issue	
Kentucky	A rated; Z rated ⁴ on a case-by-case evaluation	Two TE versions	Two generic versions		Case-by-case if availability is an issue	
Louisiana	A rated	Three TE versions	Number of generic versions not provided	Three manufacturers		
Maine ⁵	Did not use any of the above criteria					
Maryland	A rated		Two generic versions	Two generic manufacturers		
Massachusetts ⁶	Did not use any of the above criteria					
Michigan	A rated; Z rated on a case-by-case evaluation	Two TE versions		Two generic manufacturers	Case-by-case if availability is an issue	
Minnesota			One generic version		Available from major wholesalers	

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Table D-1: Criteria States Use To Select Drugs Included in MAC Programs (Continued)

State	Criteria					
	Approval Rating	Therapeutic Equivalence	Minimum Number of Available Generics	Manufacturer Supply	Pharmacy Availability	Drug Cost
Montana	A rated	Number of TE versions not specified	Two generic versions	Three rebate-eligible manufacturers	Readily available; monitors for shortages	Assess drug's net cost
Nebraska					Readily available	Assess if cost less than estimated acquisition cost
New Hampshire	A rated; Z rated on a case-by-case evaluation	Two TE versions		Two generic manufacturers	Case-by-case if availability is an issue	
New Jersey	A rated					
New Mexico				Two manufacturers		
New York	A rated; Z rated on a case-by-case evaluation	Two TE versions		Two generic manufacturers	Case-by-case if availability is an issue	
North Carolina	A rated	Number of TE versions not specified	One generic version	Two rebate-eligible manufacturers	Readily available	Assess drug's net cost
North Dakota	Did not use any of the above criteria					
Ohio	A rated	Number of TE versions not specified		Two manufacturers		
Oklahoma			Two generic versions	Three generic manufacturers		

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Table D-1: Criteria States Use To Select Drugs Included in MAC Programs (Continued)

State	Criteria					
	Approval Rating	Therapeutic Equivalence	Minimum Number of Available Generics	Manufacturer Supply	Pharmacy Availability	Drug Cost
Rhode Island			Number of generic versions not provided	Three manufacturers		
South Carolina	A rated; Z rated on a case-by-case evaluation	Two TE versions		Two generic manufacturers	Case-by-case if availability is an issue	
South Dakota				Two generic manufacturers		
Tennessee	A rated	All versions are TE	Two generic versions	Two manufacturers	Readily available	
Texas	AA or AB rated		Three generic versions	Three generic manufacturers	Available in wholesalers	
Utah			One generic version			
Vermont	A rated	All versions are TE	Two generic versions	Two rebate-eligible generic manufacturers	Readily available	
Virginia	AB rated			Three manufacturers		
Washington	Did not use any of the above criteria					
West Virginia				Three manufacturers		
Wisconsin	A rated	Number of TE versions not specified	One generic version	Two manufacturers	Readily available; monitors for shortages	

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Table D-1: Criteria States Use To Select Drugs Included in MAC Programs (Continued)

State	Criteria					
	Approval Rating	Therapeutic Equivalence	Minimum Number of Available Generics	Manufacturer Supply	Pharmacy Availability	Drug Cost
Wyoming ⁷			One generic version	One manufacturer	Currently available	Must have at least two drug-cost references
Number of States	28	21	29	32	21	7

Source: Office of Inspector General (OIG) analysis of State survey responses, 2012.

¹ An "A"-rated drug is one that FDA considers to be therapeutically equivalent to other pharmaceutically equivalent products. Subcategories within the "A" rating include "AA" and "AB" ratings.

² The District of Columbia requires that a drug have at least three claims in the prior quarter for it to be included on its MAC list.

³ Delaware also requires that a drug have a least 75 claims per quarter for it to be included on its MAC list.

⁴ A "Z" rating is not an official rating by FDA but through First DataBank, which supports databases for drugs. A "Z" rating is generally used by drug companies to designate drugs approved under different labels, drugs not in FDA's Orange Book, or brand drugs with no available generics.

⁵ Maine requires that a drug have an active, rebateable NDC that is available to pharmacies for it to be included on its MAC list.

⁶ Massachusetts requires that a drug have at least four claims in the past 90 days for it to be included on its MAC list.

⁷ Wyoming also requires that the drug have potential use in the Medicaid outpatient population for it to be included on its MAC list.

Table D-2: Number of Drugs Covered on States' MAC Lists

State Medicaid Agency	Drug Code Used	Number of Covered Drugs (By Code)	Number of Covered GCNs
Alabama	Generic Sequence Number (GSN)	3,385	3,384
Alaska	Codes Not Provided	N/A ¹	N/A
Arkansas	GCN and National Drug Codes (NDC)	1,122 GCNs 252 NDCs	1,217
Colorado	GCN	2,684	2,684
Connecticut	Codes Not Provided	N/A	N/A
District of Columbia	GCN	1,479	1,479
Delaware	Generic Formulation Code	2,170	N/A
Florida	Codes Not Provided	N/A	N/A
Georgia	Group Product Identifiers (GPI)	1,593	N/A
Hawaii	GCN ²	1,446	1,446
Illinois	GCN ³	1,743	1,743
Indiana	GCN	1,658	1,658
Iowa	GCN	1,327	1,327
Kansas	GCN	1,325	1,325
Kentucky	Codes Not Provided	N/A	N/A
Louisiana	GSN	1,157	1,157
Maine	GPI ⁴	2,550	N/A
Maryland	NDC	29,419	1,691
Massachusetts	GCN	5,355	5,355
Michigan	GSN	2,237	2,105
Minnesota	GSN	2,082	2,080
Missouri	GCN	1,388	1,388
Montana	GCN	494	494
Nebraska	GSN	3,727	3,677
New Hampshire	Codes Not Provided	N/A	N/A

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Table D-2: Number of Drugs Covered on States' MAC Lists (Continued)

State Medicaid Agency	Drug Code Used	Number of Covered Drugs (By Code)	Number of Covered GCNs
New Jersey	GCN	2,122	2,122
New Mexico	GCN	2,442	2,442
New York	GCN	2,090	2,090
North Carolina	GCN	1,388	1,388
North Dakota	GSN	2,048	2,048
Ohio	GCN	926	926
Oklahoma	GCN	2,017	2,017
Pennsylvania	GCN	1,469	1,469
Rhode Island	Codes Not Provided	N/A	N/A
South Carolina	Codes Not Provided	N/A	N/A
South Dakota	GCN ⁵	1,846	1,846
Tennessee	GPIs and Codes Not Provided	At least 1,526 ⁶	N/A
Texas	GSN ⁷	1,158	1,158
Utah	GSN ⁸	1,728	1,727
Vermont	GPI	1,885	N/A
Virginia	Codes Not Provided	N/A	N/A
Washington	GCN	1,495	1,495
West Virginia	GSN	1,349	1,349
Wisconsin	GSN	1,870	1,864
Wyoming	GCN ⁹	1,592	1,592

Source: OIG analysis of State MAC spreadsheets, 2012.

¹ N/A indicates that we were unable to crosswalk the code to a GCN or a drug code was not provided.

² Hawaii also provided the corresponding NDC for each GCN on its spreadsheet.

³ Illinois also provided the corresponding GSN for each GCN on its spreadsheet.

⁴ Maine also provided the corresponding NDC for a select number of GPIs on its spreadsheet.

⁵ South Dakota also provided the corresponding GPI for each GCN on its spreadsheet.

⁶ Tennessee set MAC prices using GPIs for most drugs. However, it also had a separate MAC list for drugs covered under the \$4 generic program; the State did not provide drug codes for these drugs.

⁷ Texas provided GSNs on its MAC spreadsheet. However, the State has created its own drug code to set MAC prices.

⁸ Utah also provided the corresponding NDC for each GSN on its spreadsheet.

⁹ Wyoming also provided the corresponding GSN for each GCN and the corresponding NDC for select GCNs on its spreadsheet.

APENDIX E

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUL -9 2013

TO: Daniel R. Levinson
Inspector General

FROM: MaTlyn Tavenner /S/
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Medicaid Drug Pricing in State Maximum Allowable Cost Programs" (OEI-03-11-00640)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the above-referenced OIG draft report. In January 2012, OIG surveyed the 45 states (including the District of Columbia) with Maximum Allowable Cost (MAC) programs to identify the methods and criteria used to set MAC prices on multiple source drugs in the state. OIG compared states' criteria for selecting drugs and setting prices in their MAC programs and also calculated the aggregate percentage difference between each state's MAC prices and the federal upper limit (FUL) amounts in effect for the first quarter of 2012 based on published prices, as well as the draft FUL amounts set by the Affordable Care Act (ACA) based on average manufacturer prices (AMP). Finally, OIG identified the state with the most aggressive MAC program and calculated the potential national savings had all states used this program.

OIG Findings

Most of the 45 states with MAC programs used acquisition cost to set MAC prices. OIG found the aggregate pre-ACA FUL amounts were, on average, nearly double state MAC prices in January 2012. However, the aggregate post-ACA FUL amounts were lower, on average, than MAC prices. Although the new FUL amounts were required to take effect in October 2010, as of May 2013, CMS had not implemented them. Unlike the FUL program, state MAC programs provide states the flexibility to set their own coverage requirements. As a result, state MAC programs cover significantly more drugs than are covered under the FUL program. Lastly, states could achieve additional cost savings by using more aggressive MAC pricing formulas and inclusion criteria.

Specifically, this report found that for the study period:

- Most states with MAC programs used pharmacy acquisition cost to set their MAC prices.
- Aggregate pre-ACA FUL amounts, on average, were almost double than state MAC prices; however, the post-ACA FUL amounts were lower than state MAC prices, in the aggregate.
- Aggregate post-ACA FUL amounts were, on average, 22 percent lower than state MAC prices.

- States exercised their flexibility to establish MAC coverage criteria which resulted in a wide range of drugs subject to a MAC price.
- State MAC programs covered significantly more drugs than the FUL program.
- On average, 60 percent of the drugs covered by 32 states' MAC programs were not covered by the pre-ACA FUL program.
- On average, 53 percent of the drugs covered by states' MAC programs were not covered by the post-ACA FUL program.
- States may achieve additional cost savings by using different MAC pricing formulas and inclusion criteria.
- Fourteen states could have reduced their generic spending by more than 20 percent by using one particular states' MAC program.

OIG Recommendation

To ensure that Medicaid drug cost-containment strategies are maximized, OIG recommends that CMS complete the implementation of post-ACA AMP-based FUL amounts.

CMS Response

The CMS concurs with OIG's recommendation and plans to finalize these FULs in the near future.

OIG Recommendation

To ensure that Medicaid drug cost-containment strategies are maximized, OIG recommends that CMS encourage states to reevaluate their MAC programs to identify additional cost saving opportunities.

CMS Response

The CMS concurs with OIG's recommendation to encourage states to reevaluate their MAC programs and plans to release an informational bulletin to the states on this in the near future.

Again, we appreciate the opportunity to review and comment on this draft report and look forward to working with OIG on this and other issues.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office.

Stephanie Yeager served as the team leader for this study, and Stefanie Vance served as the lead analyst. Central office staff who provided support include Althea Hosein, Kevin Manley, and Christine Moritz. Staff from the Dallas regional office who provided support include Leah Bostick.

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