Proposed MAC Legislation
May Increase Costs of Affected Generic Drugs
By More Than 50 Percent

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Executive Summary

MAC (Maximum Allowable Cost) is a savings tool used by Medicare, Medicaid, large employers, and other health plans in order to prevent overpayments for generic prescriptions. A MAC is simply the maximum amount that a health plan will reimburse a pharmacy for a given strength and dosage form of a particular generic drug. A drugstore that participates in a plan's pharmacy network has contractually agreed to accept the plan's MACs (along with dispensing fees) as reimbursement for generic prescriptions.

MACs are needed because generics—unlike brands—often have inflated manufacturer "list" prices that don't reflect a pharmacy's actual cost to buy the product. To determine MACs, plans research the actual prices that pharmacies pay to purchase generic medications. Without MACs, drugstores could earn excess profits by dispensing generic drugs with the highest list prices. MACs have proven highly successful at saving money for both government programs and private-sector health plans.

A recent analysis from the HHS, Office of Inspector General (OIG) demonstrated "the significant value MAC programs have in containing Medicaid drug costs." The OIG recommended that states strengthen MAC programs. In contrast, some states are considering legislation that would restrict the use of MAC programs for many hundreds of drugs.

Based on Visante's analysis of more than 800 drugs that are likely to be impacted by legislation restricting the use of MACs, we find:

- MAC legislation could increase costs by 31% to 56% for affected generic prescriptions.

- If MAC legislation were enacted nationwide, expenditures on generic prescriptions could increase by up to $6.2 billion annually.

- States implementing MAC legislation could see overall drug costs increase by 2%.

These findings are based on legislation prohibiting the use of MACs for non A-rated generics and generics that have fewer than three nationally available, therapeutically equivalent, multiple source products. In the absence of MACs, reimbursement for these drugs would be more costly.

We believe the above estimates are conservative and that the actual cost of MAC legislation could well be higher and would likely be passed on to state health programs, businesses, and unions in the form of higher health plan costs and increased patient out-of-pocket expenditures.

Discussion

Introduction

MAC (Maximum Allowable Cost) programs are common cost management tools specifying the reimbursement limit for a particular strength and dosage of a generic drug. PBMs and plan sponsors use MACs to calculate appropriate reimbursement rates that prevent overpayments for generic prescriptions.

MAC price lists are widely used by health plans and PBMs to reduce costs for private-sector clients, union health and welfare funds, Medicaid and Medicare Part D.

- MACs are used by 74% of private-employer prescription drug plans for retail generic prescriptions.[1]

- States adopted MAC lists after government audits showed that Medicaid reimbursements for generic drugs far exceeded a pharmacy's acquisition costs.[2]

- Forty-five state Medicaid programs now use MAC lists, up from 26 states in 1999.[3, 4]

Proposed Legislation

MAC legislation often identifies two groups of drugs for which a MAC would be prohibited:

1. Non A-rated generics (ratings from FDA's Orange Book), and

2. Generics that have fewer than three nationally available, therapeutically equivalent, multiple source generic products.

PBMs and plan sponsors routinely apply MACs to these groups of drugs.

The FDA lists a variety of rating designations in the Orange Book, and PBMs apply MACs to many or most of them. Additionally, PBMs and health plans also apply MACs to unrated generic drugs (sometimes called "Z," "NR" or "NA"-rated generics), which are not listed in the Orange Book and include older drugs not evaluated by the FDA (e.g., phenobarbital).

In short, PBMs and health plans frequently use MAC lists for products with fewer than three nationally available drugs. Without MACs, reimbursement is typically based on Average Wholesale Price (AWP).

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[1] Pharmacy Benefit Management Institute, 2014-2015 Prescription Drug Benefit Cost and Plan Design Report, December 2014.

[2] Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer, Office of Inspector General, OEI-03-05-00110, June 2005. Available at http://oig.hhs.gov/oei/reports/oei-03-05-00110.pdf.

[3] Pharmaceutical Benefits Under State Medical Assistance Programs 1999, National Pharmaceutical Council.

[4] Medicaid Drug Pricing In State Maximum Allowable Cost Programs, Office of Inspector General, OEI-03-11-00640, August 2013. Available at http://oig.hhs.gov/oei/reports/oei-03-11-00640.pdf.

The Problem with Basing Reimbursement for Generics on AWP

Unlike brand drugs with stable pricing benchmarks for reimbursement, there is no stable marketplace benchmark for generic drugs. Multiple manufacturers of the same product price their generic drugs differently and generic drugs often have a huge range of AWPs. MACs reconcile the differences between an inflated AWP and the price the pharmacy actually pays.

Three points should be kept in mind with regard to MACs and AWPs:

- Each manufacturer of a generic drug makes an identical version of the drug that is the same as a brand name drug in dosage, safety, strength, and quality.

- Each drug manufacturer establishes its own AWP for a particular strength and dosage of a generic drug and these list prices can vary widely.

- A MAC list creates a standard reimbursement amount for identical products, regardless of the manufacturers' varying list prices.

In order to illustrate the significant variability in AWP prices, Visante compared AWP to Wholesale Acquisition cost (WAC) for the 1,727 unique drugs identified by the national drug code (NDC) included in our analysis.[5] The AWPs were greater than WAC for all the affected drugs included in the analysis. The vast majority (85%) of AWPs were between one and two times WAC. In other words, if WAC was $100, then AWP was typically $100-200. Some drugs had AWPs much greater than two times WAC. In fact, three percent of the NDCs in our analysis had AWPs five to 20 times greater than WAC.

MACs are an important pharmacy benefit management tool which takes this enormous AWP variability out of the reimbursement equation.

OIG Report Recommends Strengthening State Medicaid MAC Programs

A recent report from the HHS OIG,[6] published in August 2013 reaffirmed the value of MACs for state Medicaid programs and recommended that states should strengthen their MAC programs to realize additional cost savings.

Below are a few notable excerpts from the OIG report:

> *"Our findings demonstrate the significant value MAC programs have in containing Medicaid drug costs. To maximize Medicaid drug cost-containment strategies, we recommend that CMS encourage states to reevaluate their MAC programs to identify additional cost-saving opportunities.*

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[5] Medi-Span®.

[6] Medicaid Drug Pricing In State Maximum Allowable Cost Programs, Office of Inspector General, OEI-03-11-00640, August 2013. Available at http://oig.hhs.gov/oei/reports/oei-03-11-00640.pdf.

> *CMS concurred with (the OIG) recommendations. CMS plans to release an informational bulletin that encourages states to reevaluate their MAC programs for cost-saving opportunities in the near future."*

The OIG report also looked at "best practices" among the state MAC programs, and found that 39 states could have saved almost $1 billion in 2011 by using one state's MAC program:

> *"States 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.*
>
> *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. We found that 39 of 45 States would have saved $483 million in the first half of 2011 had they used Wyoming's MAC program.*
>
> *Fourteen States could have reduced spending on generic drugs by more than 20 percent had they used Wyoming's MAC program. Another 18 states could have reduced spending by 10-20%."*

Based on OIG identifying Wyoming as a state using best practices with respect to MACs, Visante analyzed the potential impact that MAC legislation could have on that state's program. We found that 284 of the 834 MAC-affected drugs appeared on the Wyoming MAC list in April 2013. In other words, if a typical anti-MAC bill was proposed in Wyoming, it would eliminate 284 drugs from Wyoming's list of 1,932 drugs with MACs as of April 2013, or roughly 15% of drugs on Wyoming MAC list.

MAC Legislation Analysis

How Are Prices For Non-MAC Generics Determined?

Visante interviewed industry experts with knowledge of MAC programs in the largest PBMs and health plans. Our findings indicate that reimbursements for non-MAC generic drugs are typically based on:

1. A calculated price based on AWP less a discount of 16-25% plus a dispensing fee, or

2. The Usual-and-Customary (U&C) price charged by the pharmacy (i.e., the cash price charged to patients who do not have prescription coverage).

Which Drugs Would Be Affected By Proposed MAC Legislation?

Visante identified 834 prescription drug products that would be affected by proposed legislation restricting MACs. These drugs represent approximately 3.6% of total drug prescription drug

sales during the first half of 2013.[7] Visante then identified the subset of these drugs that also appear in the most recent National Average Retail Price (NARP) survey published in June 2013.[8] We compared the third-party prices to the cash prices reported by NARP. We also calculated the AWP-based reimbursement which might have been paid in the absence of MAC, and compared to the third-party price listed in NARP. We assume that NARP third-party prices reflect the use of MACs.

Visante's analysis assumes the third-party prices reported by NARP reflect the use of 100% MACs, but since MACs are not applied to all these drugs by all third-party plan sponsors, the third-party prices listed in NARP actually reflect a <u>mix</u> of MACs and AWP-based prices. Because Visante does not have visibility to the relative mix of MAC vs AWP prices for each drug, we do not have a methodology for adjusting for this mix in our analysis. Because the third-party prices reported by NARP are probably higher than a "pure 100% MAC price," Visante's predicted cost increases are conservative. In other words, the actual cost increases associated with eliminating MACs for affected drugs would likely be higher than Visante estimates.

Results: Proposed MAC Legislation Would Increase Costs for Affected Drugs by 31-56%

If proposed MAC legislation were passed – eliminating MACs on the 834 drugs identified in our analysis – the cost of these affected drugs would increase by 31-56%, depending on which "alternative price" was substituted for the MAC price.

Because these drugs represent approximately 3.6% of total drug spend, such legislation could increase total drug spend from 1.1% to 2.0%. Applying this percentage increase to the projected total Rx drug expenditures in 2015 for the United States of $309 billion[9] would result in a potential annual cost increase of $3.4 to $6.2 billion.

Table 1: Potential Cost Impact of Proposed MAC Legislation

If MAC Price Increased To…	Percent Cost Increase for Affected Drugs	Percent Increase in Total Rx Drug Expenditures	Potential Impact on US Rx Drug Spend In 2015
Cash Price (U&C)	31%	1.1%	$3.4 billion
AWP-25% + Disp Fee	40%	1.4%	$4.4 billion
AWP-16% + Disp Fee	56%	2.0%	$6.2 billion

Appendix A summarizes the potential cost increases for each state, assuming a 2% annual increase in total drug expenditures.

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[7] Based on commercially available prescription sales data for the time period Jan-Jun 2013.

[8] National Average Retail Prices (NARP) reflects prices paid for drugs to retail community pharmacies for individuals with third party insurance (includes Medicaid managed care and Medicare Part D), Medicaid, cash paying customers. Effective July 1, 2013, CMS suspended the NARP survey, pending funding decisions. http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html.

[9] CMS Projected National Health Expenditures, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.

Methodology

Visante's analysis can be summarized in five steps:

1. Identify drugs which would be affected by proposed MAC legislation;

2. Compare prices for affected drugs;

3. Calculate weighted average cost increases based on prescription utilization data;

4. Calculate portion of total drug spend represented by 834 affected drugs; and

5. Calculate total drug spend for 2015 for US and individual states, and projected annual cost increase for US and individual states.

Below are descriptions of the data sources and methodology used in each step of the analysis.

1. *Identify drugs which would be affected by proposed MAC legislation*

Visante identified the prescription drug products that would be affected by proposed MAC legislation, targeting two groups of drugs for which a MAC would be prohibited:

a) Non A-rated generics, and

b) Generics that have fewer than three nationally available, therapeutically equivalent, multiple source products.

In the absence of a MAC, these drugs would be reimbursed at higher rates. Visante started with Medi-Span drug file[10] on all drug products in the United States (more than 225,000 11-digit NDC #'s), and eliminated products which would NOT likely be affected by proposed MAC legislation (i.e., inactive, OTC, repackagers, various injections/infusions/surgical products, single-source brands, and brands with fewer than two generics available). We then consolidated the NDC-11 data down to NDC-9 data and eliminated any duplicates, leaving 10,096 unique multisource drug products. We separated these products into A-rated/bioequivalent products vs non-A-rated products. Finally, we eliminated all products with three or more A-rated generic manufacturers (since these would be unaffected by proposed MAC legislation), leaving 827 9-digit NDCs for A-rated products with 1-2 generic manufacturers, and 880 9-digit NDCs for non-A-rated products. These 1,727 products (9-digit NDCs) represent the 834 generic drugs that would be affected by proposed MAC legislation or, in other words, an average of about two manufacturers per generic drug.

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[10] Medi-Span® drug file (including AWP and WAC prices) for April 2013.

2. *Compare prices for affected drugs*

Visante's analysis focused on the time period Jan-Jun 2013, because NARP data was available for that time period. CMS discontinued publication of NARP data on July 1, 2013.

Visante reviewed published surveys and conducted structured interviews with industry experts in order to assess the impact of MAC legislation. Our findings indicate that reimbursement for non-MAC generic drugs can be based on some combination of:

1. A calculated price based on AWP less a percent discount plus a dispensing fee:

    a. Some plans apply their normal AWP formula for brand drugs, which, according to one published employer survey, is reported to be AWP-16% plus a $1.87 dispensing fee.[11]

    b. Some plans may apply a deeper AWP discount specific to "non-MAC generics," which may be in the range of AWP-25% plus a dispensing fee.

2. The Usual-and-Customary (U&C) price charged by the pharmacy (i.e., the cash price charged to patients without prescription coverage).

Therefore, Visante compared four prices for all affected drugs with available NARP data.

1. NARP reported Average third-party prescription price (the proxy for MAC price).

2. NARP reported Average Cash prescription price.

3. Visante calculated AWP-based prescription price.

    a. (AWP-16%) x Quantity + $1.87
    b. (AWP-25%) x Quantity + $1.87

The last NARP survey was published in June 2013, based on claims data from April 2013. This report listed the average third-party prescription prices for 4,435 different products (3,933 generics and 502 brands). It also listed the average cash prescription prices for 2,026 different products (1,902 generics and 124 brands).

Visante compared our list of potential MAC-affected products to the NARP list, and matched 226 NDCs on the NARP list, representing 168 generic drugs. For these 226 NDCs, we calculated the AWP-based reimbursement (in the absence of MAC) based on the formulas listed above. AWP unit prices were based on the Medi-Span file from April 2013.

We then compared these AWP-based prices to the average third-party and cash prescription prices reported by NARP using the "quantity most frequently dispensed" reported by NARP.

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[11] Pharmacy Benefit Management Institute, 2014-2015 Prescription Drug Benefit Cost and Plan Design Report, December 2014.

3. *Calculate weighted average cost increases based on prescription utilization data for affected drugs*

   Visante used commercially available prescription utilization data (retail prescriptions only, not including mail), for the time period Jan-Jun 2013, to weight the relative impact of potential cost increases on all 226 NDCs. For example, if the average prescription cost for Drug A increases 100%, but Drug A only has 100 prescriptions, and the average prescription cost for Drug B increases only 50% but has 100,000 prescriptions. Clearly, Drug B will have the larger impact on total drug spend, even though its individual percentage cost increase is smaller.

   The weighted average total cost increase ranged from 31% to 56% (see Table 2).

4. *Calculate portion of total drug spend represented by 834 affected drugs*

   Visante used prescription sales data (retail only, not including mail), for the time period Jan-Jun 2013, to estimate the relative impact these 834 MAC-affected drugs may have on total annual drug spend in the United States. According to these data, the drugs affected by proposed MAC legislation represent 3.6% of prescription drug sales.

   Therefore, a cost increase of 31-56% for these affected drugs might increase total drug spend by 1.1% to 2.0%.

5. *Calculate total drug spend projected annual cost increase for US and individual states*

   According to Projected National Health Expenditures published by the Centers for Medicare and Medicaid Services (CMS),[12] annual prescription drug expenditures in the US in 2015 will reach $309 billion. Multiplying the percentage increases calculated in Step 4 above yields a potential spending increase of $3.4 to $6.2 billion (see Table 2).

   The most recent CMS data on Rx Drug Expenditures per state are from 2009. Visante applied those "percentages of national total" to these new figures to derive the cost estimates in Appendix A.

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[12] CMS Projected National Health Expenditures, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.

Table 2: Estimated Increased Drug Costs If MAC Is Eliminated for 834 Affected Drugs

If MAC Rx Price Increased to...	% Cost Increase for Affected Drugs [1]	% Impact on Total Rx Drug Spend [2]	Potential Impact on Annual US Rx Drug Spend for 2015 [3]
Cash price [4]	31%	1.1%	$3.4 billion
AWP-25%+disp fee [5]	40%	1.4%	$4.4 billion
AWP-16%+disp fee [6]	56%	2.0%	$6.2 billion

[1] Weighted based on 226 "MAC-affected NDC's" w NARP data

[2] 834 drugs (1727 9-digit NDC's) acct for 3.6% total Rx spend (data from IMS Health)

[3] % impact applied to estimated 2014 Rx expenditures (CMS National Health Expenditures)

[4] Cash Rx prices (from NARP) for 130 of the 226 MAC-affected drugs with NARP data

[5] Some plans may use a special formula specific to non-MAC generics

[6] Some plans may use reimbursement formula for brands for non-MAC generics

APPENDIX A: Potential Cost Increases Related To Proposed MAC Legislation by State

Potential Cost Impact of Proposed MAC Legislation
Impact of Anti-MAC Legislation on Prescription Drug Expenditures
$ millions

State	Prescription Expenditures (2015)	Increased Total Prescription Expenditures	State	Total Prescription Expenditures (2015)	Increased Total Prescription Expenditures
United States	**$309,300**	**$6,243**			
Alabama	$5,855	$118.2	Montana	$753	$15.2
Alaska	$604	$12.2	Nebraska	$1,818	$36.7
Arizona	$5,587	$112.8	Nevada	$2,487	$50.2
Arkansas	$2,923	$59.0	New Hampshire	$1,403	$28.3
California	$30,579	$617.2	New Jersey	$10,739	$216.7
Colorado	$3,653	$73.7	New Mexico	$1,674	$33.8
Connecticut	$4,706	$95.0	New York	$22,896	$462.1
Delaware	$1,137	$22.9	North Carolina	$10,093	$203.7
District of Columbia	$573	$11.6	North Dakota	$807	$16.3
Florida	$23,680	$477.9	Ohio	$10,880	$219.6
Georgia	$8,996	$181.6	Oklahoma	$3,652	$73.7
Hawaii	$1,360	$27.5	Oregon	$3,328	$67.2
Idaho	$1,205	$24.3	Pennsylvania	$14,794	$298.6
Illinois	$11,685	$235.8	Rhode Island	$1,372	$27.7
Indiana	$6,217	$125.5	South Carolina	$4,553	$91.9
Iowa	$3,083	$62.2	South Dakota	$657	$13.3
Kansas	$2,443	$49.3	Tennessee	$6,915	$139.6
Kentucky	$4,424	$89.3	Texas	$23,135	$466.9
Louisiana	$5,172	$104.4	Utah	$2,175	$43.9
Maine	$1,563	$31.5	Vermont	$557	$11.2
Maryland	$6,669	$134.6	Virginia	$7,574	$152.9
Massachusetts	$7,183	$145.0	Washington	$5,683	$114.7
Michigan	$9,554	$192.8	West Virginia	$2,258	$45.6
Minnesota	$5,032	$101.6	Wisconsin	$5,377	$108.5
Mississippi	$2,947	$59.5	Wyoming	$493	$9.9
Missouri	$6,399	$129.2			

This analysis projects that a 56% increase in costs for affected drugs will result in a 2% increase in total prescription drug spending for each state.
National projections based on CMS NHE Rx Expenditures for 2015 (published 2014)
State-by-state % breakdown based on most recent CMS NHE Rx spend by state (2009)