

**The Unintended Consequences of Restrictions on the Use of
Maximum Allowable Cost Programs (“MACs”) for Pharmacy Reimbursement**

David A. Hyman
H. Ross & Helen Workman Chair in Law
Professor of Medicine
University of Illinois

April 2015

Executive Summary

At one time, public and private payers relied on cost-based reimbursement to compensate health care providers. However, cost-based reimbursement resulted in dramatic increases in health care spending, because providers had no incentive to shop around for the least costly goods or devise the most efficient way to provide services. In response, payers have largely abandoned cost-based reimbursement, and adopted other strategies. One common strategy is to pay the estimated average market price for the goods or services that have been provided.

Pharmaceuticals exemplify this phenomenon. Public and private payers originally paid list price for dispensed pharmaceuticals – but it became clear that the list price for most generic drugs was (and is) substantially higher than the actual acquisition cost incurred by pharmacies. In response, public and private payers developed “Maximum Allowable Cost programs (“MACs”) to determine the reimbursement for dispensed generic pharmaceuticals. MACs are set at a level reflecting the average acquisition cost of a well-run pharmacy. MACs encourage pharmacies to purchase generics at the lowest possible cost, thereby intensifying competition among wholesalers and drug manufacturers, and lowering overall pharmaceutical spending.

In the private sector, MACs are governed by participating pharmacy agreements (“PPAs”), between pharmacy benefit managers (“PBMs”) and pharmacies. PPAs specify how pharmacies will be reimbursed, detail the nature of any MACs that might apply, and spell out the process for resolving any disputes.

MACs have several predictable effects:

- Increase dispensing of generics;
- Ensure pharmacies are not overpaid for dispensing generics;
- Make the generic market more competitive and more efficient.

Legislative or regulatory measures that limit, restrict, or interfere with MACs are likely to have several unintended adverse consequences:

- Restricting the use of MACs is likely to increase costs;
- Requiring specific methods and timeframes for MAC appeals and payment adjustments – including requiring “retroactive” payments – is likely to result in administrative complexity, higher costs, and unpredictability;
- Requiring public disclosure of MACs and MAC methodologies is likely to lead to tacit collusion and higher prices.

The Unintended Consequences of Restrictions on the Use of Maximum Allowable Cost Programs (MACs) for Pharmacy Reimbursement

Why Payers Developed MACs

Currently, generics account for 86% of filled prescriptions. In general, the more generics that are available, the lower the price at which the drug can be purchased by pharmacies. However, pricing is volatile; various supply-side and demand-side factors affect pricing.¹

“List” prices for generics are often substantially higher than the actual acquisition cost incurred by retail pharmacies. This is primarily attributable to (a) the product life cycle of generics and (b) competition within the pharmaceutical supply chain. Given these dynamics, payers developed MACs to avoid overpaying for generics.

Why List Prices Exceed Actual Acquisition Costs

A generic pharmaceutical’s life cycle typically starts with a 180-day period of marketing exclusivity, which is granted to the first generic approved by the Food and Drug Administration (FDA).² During this 180-day period, the first-approved generic competes only with the brand name version of the product and any “authorized generics” that the brand manufacturer either makes itself or allows on the market through licensing agreements.

If only one generic is available during the 180-day period, pharmacies can typically acquire the drug for about 20% less than the brand price.³ If “authorized generics” are also available, the competition is greater – so the pharmacy’s acquisition cost may be 30% less than the brand price.⁴ Drug wholesalers also seek to negotiate discounts – which can be as high as 40-50% when an authorized generic is available.⁵ In a competitive market, these discounts will be passed on to pharmacies. However, the list price does not typically reflect the impact of these discounts.

Once the 180-day exclusivity period ends, the market is open to any generic approved by the FDA, and dramatic savings can result. For highly prescribed medications, many generics will enter the market. For example, after the 180-day exclusivity period ended for the first generic version of the Lexapro (a popular anti-depressant), eleven additional generics were approved by the FDA.⁶ The additional competition drove the price per 10

¹ Of late, there has been a significant run-up in the cost of some generic drugs. See Jonathan D. Alpern, William M. Stauffer, and Aaron S. Kesselheim, *High-Cost Generic Drugs — Implications for Patients and Policymakers*, 371 *New Engl. J. Med.* 1859 (2014) (“Numerous factors may cause price increases for non-patent-protected drugs, including drug shortages, supply disruptions, and consolidations within the generic-drug industry.”)

² To secure this marketing exclusivity, the generic drug company must also file what is known as a “paragraph IV certification.” This document indicates that the generic drug company believes any applicable patents are either invalid or will not be infringed.

³ Fein, A.J., *2014-15 Economic Report on Retail, Mail, and Specialty Pharmacies*, Drug Channels Institute, January 2015, at 129.

⁴ *Ibid* at 129-130.

⁵ *Ibid.* at 130.

⁶ *Ibid.*

mg pill down from \$2.63 to \$0.16 within a month – a 94% decrease.⁷ Again, the list price does not reflect the impact of these price drops.

After 1-2 years, the market for a particular generic drug matures. Some manufacturers may exit due to low margins or an eroding market for the drug, or as newer medications in the same class also become available in generic form.⁸ If there are too few manufacturers, prices can increase. Prices will also increase in the event of shortages, whether due to manufacturing problems or interruptions in the supply of an active ingredient. Once again, the list price does not reflect the impact of this pricing volatility.

Wholesaler Discounting and MACs

Payers also use MACs to ensure that pharmacy reimbursement takes account of any discounts that result from competition within the pharmaceutical supply chain. For example, wholesalers may provide discounts to pharmacies that purchase a minimum quantity of generic drugs. Alternatively, wholesalers can provide discounts on brand name drugs as long as the pharmacy purchases a minimum volume of generic drugs. Drug wholesalers offer these incentives because they earn a disproportionate share of their profits from generics; in 2014, generics generated 16% of their revenue but 75% of their profits.⁹

To enhance their negotiating leverage, independent pharmacies often join together in buying groups to concentrate their purchases with one or more preferred vendors. In exchange for the buying group selecting a wholesaler as its preferred vendor, the wholesaler may agree to provide discounts on the group's consolidated purchases. Some of these discounts may be paid as a quarterly rebate based on the aggregate volume of generics purchased by the group.¹⁰

None of the discounts and rebates that result from competition within the pharmaceutical supply chain are typically reflected in the list prices for generics.

How State Medicaid Programs Developed MACs and Use Them Today

MACs first emerged in the Medicaid program. Both state and federal regulations govern the amount that Medicaid can reimburse for prescription drugs. At the outset, reimbursement generally involved paying the lesser of the estimated acquisition cost (EAC) plus a reasonable dispensing fee, or the providers' usual and customary charges to the general public. The EAC was typically determined based on published prices – including the Average Wholesale Price (“AWP”).

At one time, the AWP reflected pharmacy's acquisition costs, but, it quickly became apparent that there was considerable divergence between the AWP and pharmacists' true acquisition cost, particularly when generic drugs became more prevalent. Once this became clear, it was necessary to modify Medicaid's reimbursement formula, to ensure the amounts paid reflected pharmacists' actual costs (i.e., the acquisition cost plus the costs associated with dispensing the pharmaceutical).

⁷ Ibid. at 130-131.

⁸ Ibid. at 131.

⁹ Ibid. at 113.

¹⁰ Ibid. at 112.

In 1987, the federal government responded by requiring states to implement an aggregate payment limit for specific drugs.¹¹ The payment limit was determined mechanically.¹² Pursuant to this payment limit, the dispensing pharmacy was paid a flat amount, *irrespective of its actual acquisition cost for the drug in question*. However, there were serious concerns that the payment limits were still too high. States responded by modifying their existing payment formulas, and adopting maximum allowable cost (“MAC”) programs.

State MAC programs were similar to the federal payment limit, but they applied to a far broader array of drugs, and set lower reimbursement levels.¹³ Medicaid MACs are calculated based on aggregate figures that reflect pharmacies’ average acquisition cost for a given pharmaceutical product. As of January 12, 2012, approximately 45 states used MACs for their Medicaid programs.¹⁴

PBMs and MAC Lists

PBMs adopted their own MACs, based in part on programs pioneered by state Medicaid programs. Each PBM decides which drugs to include on their MAC list, with the reimbursement level determined based on multiple factors. And, PBMs can maintain multiple MAC lists, each tied to the requirements of a particular employee benefit plan or other payer.

PBMs use contracts to create a pharmacy network. Approximately 95% of the nation’s retail pharmacies are included in one or more PBM pharmacy networks. A pharmacy that joins a network agrees to accept the terms in their contract (often called a participating pharmacy agreement (“PPA”). The PPA specifies how pharmacies will be reimbursed, details the nature of any MACs that may apply, and spells out the process for resolving disputes.

PBMs update their MAC lists on a regular basis, and rely on various public and proprietary sources to do so.

¹¹ 42 C.F.R. sec. 447.301 et seq.

¹² The Patient Protection and Affordable Care Act (“PPACA”) modified the formula for calculating a payment limit. The federal government is still in the process of implementing this change. For an estimate of the impact of these changes, see Office of Inspector General, *Analyzing Changes to Medicaid Federal Upper Limit Amounts* (Oct. 2012), available at <http://oig.hhs.gov/oei/reports/oei-03-11-00650.pdf>.

¹³ Richard G. Abramason et al, *Generic Drug Cost Containment in Medicaid: Lessons from Five State MAC Programs*, 25 Health Care Financing Review 25 (2004).

¹⁴ Office of Inspector General, *Medicaid Drug Pricing in State Maximum Allowable Cost Programs* (August 29, 2013), available at <https://oig.hhs.gov/oei/reports/oei-03-11-00640.asp>.

Effect of MAC Programs on Pharmaceutical Markets

MAC programs have had at least five distinct effects on pharmaceutical markets. First, MACs encourage pharmacies to dispense the generic version of applicable pharmaceuticals. Second, MACs heighten competition among generic manufacturers. Third, MACs ensure that pharmacies are not being overpaid for the services they provide. Fourth, MACs lower spending on pharmaceutical benefits, thereby reducing the cost of prescription drug coverage. Finally, MACs make prescription drug reimbursement more efficient.

1. Incentivizing Pharmacies to Dispense Generics

When pharmacies are only paid the amount specified in the MAC, they have a substantially increased incentive to acquire and dispense generic drugs.¹⁵ This dynamic means that a MAC will increase the share of generic drugs that are dispensed, compared to a pure cost-based reimbursement system. In the absence of a MAC, the pharmacy's incentives are quite different, since it will be paid based on a list price that often bears little resemblance to the actual acquisition cost. Under those circumstances (i.e., absent a MAC), a pharmacy that dispenses a higher-priced drug (i.e., the brand name version) will actually be paid more – increasing the cost of providing prescription drug benefits, without providing any commensurate benefits.

2. Increasing Competition Among Generic Manufacturers

When pharmacies only receive the amount specified in the MAC, they have an increased incentive to “shop for the best deal,” and find generic drugs at the lowest possible price (since they get to keep the difference between the acquisition price and the MAC). This heightens price competition among generic drug manufacturers and drug wholesalers, who know that offering lower-priced generics will help drive more sales.

Absent a MAC, pharmacies have much less incentive to buy the lowest-cost generic, since their reimbursement is based on the list price (which, as noted above, often bears little relationship to the acquisition cost). Under those circumstances, pharmacies will predictably seek to maximize the difference between the list price and their actual cost, rather than simply buying the lowest-cost generic.

3. Ensuring Pharmacies Are Not Overpaid

Cost-based reimbursement can lead to various forms of gaming that result in excess payments to pharmacies. For example, pharmacies have an incentive to dispense higher-priced drugs, particularly if they are paid a percentage mark-up on their incurred costs. MACs help prevent this behavior, and ensure that the requisite services are obtained at a level consistent with actual costs.

4. Lowering Prescription Drug Spending – and the Cost of Prescription Drug Coverage

When we combine the first three effects with the lower price at which generics are dispensed, it becomes clear that MACs help lower prescription drug spending – which in

¹⁵ Ibid. at 5 (“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.”)

turn reduces the cost of prescription drug coverage. In an analysis of Medicaid MACs, the HHS Office of Inspector General (“OIG”) concluded that MACs had “significant value” in “containing Medicaid drug costs.”¹⁶ The OIG also noted that if all states adopted the strictest MAC program then in use in 2011, generic drug spending would decline by more than 20% in fourteen states, and total Medicaid pharmaceutical spending would have been \$966 million lower.¹⁷

5. Enhanced Market Efficiency

Each drug manufacturer has its own unique list price for every dosage and variation of each drug that they sell. As discussed, these list prices vary widely, and bear little relationship to pharmacies’ actual acquisition cost. A MAC cuts through the forest of individual list prices, and specifies the reimbursement that will be paid, regardless of the list price and the actual acquisition cost. Payers need not inquire into the specifics of individual transactions, and instead simply pay the standardized amount. By eliminating the need to conduct individualized assessments, MACs help lower transaction costs and structure the market more efficiently, thereby improving system performance.

Regulatory and Legislative Efforts to Restrict MACs Will Increase Costs

A number of states have proposed or enacted legislation or regulations governing the use of MACs.¹⁸ In the name of transparency and fairness, these initiatives generally require public disclosure of each PBMs’ MACs and the methodology for arriving at the amounts that will be paid.¹⁹ Other proposals seek to constrain the ability of PBMs to develop and deploy MACs, by *inter alia* limiting the circumstances in which they may be used (i.e., by requiring a certain number of A-rated equivalents); requiring the submission of proprietary information regarding MACs to public authorities; and specifying particular methods and time-frames for MAC appeals and payment adjustments, including requiring retroactive payments. These regulatory efforts are likely to result in administrative complexity, higher costs, and unpredictability for payers.

Because MACs have been shown to lower pharmaceutical spending, restrictions on the use of MACs will lead to increases in pharmaceutical spending, and increases in the cost of prescription drug coverage. One study sought to quantify the magnitude of the increase, using a set of restrictions similar to those imposed by Iowa in H.F. 2297.²⁰ This

¹⁶ Ibid. at 21 (“Our findings demonstrate the significant value MAC programs have in containing Medicaid drug costs.”)

¹⁷ Ibid. Wyoming’s MAC program resulted in the greatest aggregate savings.

¹⁸ See, e.g., <http://www.pbmwatch.com/mac-information-center.html>

¹⁹ Some of the bills also encompass “any willing provider” provisions, and/or attempt to create the equivalent of “due process” rights for pharmacies. Although these issues lie beyond the scope of this letter, I note that the FTC has been similarly skeptical of the likely impact of such initiatives on consumers. In 2004, I co-authored a FTC advocacy letter on the subject involving a similar bill in Rhode Island that would have created “freedom of choice” for consumers and “any willing provider” protections for pharmacies. See Letter from FTC staff to Attorney General Patrick C. Lynch and Deputy Senate Majority Leader Juan M. Pichardo (April 8, 2004), available at http://www.law.illinois.edu/faculty/misc/hyman_pdfs/ribills.pdf.

²⁰ Visante, *Proposed MAC Legislation May Increase Costs Of Affected Generic Drugs By More Than 50 Percent*, January, 2015, on file with author. The study assumed that MACs would only be permissible if there were three nationally available, therapeutically equivalent, multiple source products (i.e., the branded drug, and at least two generics), and all three were A-rated.

study estimated that spending on the affected pharmaceuticals would increase by 31-56%, with a nationwide impact of \$6.2 billion increased spending annually. Importantly, this estimate captures only the immediate fiscal impact of MACs, and not the more indirect consequences.

Requiring specific methods and timeframes for MAC appeals and payment adjustments – including requiring “retroactive” payments – is also likely to have unintended effects. Such provisions will result in administrative complexity and unpredictability, which will in turn result in increased costs.

From a competition law perspective, these initiatives are unlikely to improve the performance of the pharmaceutical market, and may well make things worse. First, restrictive state-specific criteria undermine the flexibility of PBMs to develop and implement MACs. Mandatory public disclosure of MACs and the underlying methodologies will not benefit consumers, since it is likely to lead to less intensive competition, and higher prices.

More specifically, the intensity of competition is a function of various factors, including the ability of PBMs to obtain a competitive advantage by developing more effective MACs. Forced disclosure of MAC methodologies may undermine PBMs’ incentive to invest in such efforts (since other PBMs will be able to free-ride). In that environment, PBMs will be less likely to innovate – meaning that MACs will be less effective than they could be. Stated differently, compelled disclosure can create a risk to competition, which is likely to result in higher prices for consumers.

The Federal Trade Commission (“FTC”) has studied these issues extensively, issuing three detailed advocacy letters in 2004, 2006, and 2011 on the impact of mandated disclosure of PBM contract terms.²¹ The FTC and Department of Justice also issued a lengthy joint report on health care and competition policy in 2004 that discussed these issues, and a report in 2005 that provided extensive information on PBM operations.²²

In assessing these issues, it is also important to recognize the larger competitive dynamics. In designing and implementing a MAC, the PBM must balance two competing goals: it wants to ensure a broad network of pharmacies at which prescriptions may be filled (since ease of access to covered services is one of the “products” the PBM is selling), but it also has to control the cost of the covered services (since low cost is also

²¹ See Letter from FTC staff to Rep. Mark Formby (March 22, 2011), available at <http://www.ftc.gov/policy/policy-actions/advocacy-filings/2011/03/ftc-staff-letter-honorable-mark-formby-mississippi>; Letter from FTC staff to Rep. Terry G. Kilgore (October 2, 2006), available at <http://www.ftc.gov/be/V060018.pdf>; Letter from FTC staff to Rep. Greg Aghazarian (Sept. 7, 2004), available at <http://www.ftc.gov/be/V040027.pdf>. The FTC prepares advocacy letters like these in response to requests from federal and state legislators who are interested in the impact of proposed legislation on competition.

²² See, e.g., Federal Trade Commission and Department of Justice, *Improving Health Care: A Dose of Competition* (2004), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>, published commercially as *Improving Health Care: A Dose of Competition, 10 Developments in Health Economics and Public Policy* (Springer, 2005); Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* (Aug. 2005), available at <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>. To be sure, the FTC was studying a different set of issues, but the risks to competition of compelled transparency are analogous.

one of the “products” the PBM is selling). If a PBM errs in one direction (i.e., overly generous payment for pharmaceuticals), it will ensure a broad network of pharmacies, but the covered services will be less affordable – meaning the PBM may not get the business for which it is bidding. Conversely, if the PBM errs in the other direction (i.e., inadequate payment for pharmaceuticals), pharmacies will decline to contract; will drop out of the PBMs’ network; or will refuse to stock pharmaceuticals for which the MAC payment is insufficient. Employers and employees will not value a pharmacy network that is too limited along any of these dimensions – meaning the PBM may not get the business for which it is bidding.

By paying the average acquisition costs incurred by a well-run pharmacy, MACs create the necessary incentive for pharmacies to purchase and dispense the lowest-priced generics that are available in the market, thereby lowering pharmaceutical spending, and the cost of pharmaceutical coverage.

Conclusion

Current attempts to regulate MACs create significant risks to competition, and are likely to result in higher prices for consumers. Pharmacies, rather than consumers, are the primary beneficiaries of such regulation.

David A. Hyman

I am a chaired professor of law and professor of medicine at the University of Illinois. Most of my academic scholarship is on the regulation of health care financing and delivery, with a particular focus on competition law and policy. Prior to my current position, I spent three years (2001-2004) serving as Special Counsel at the Federal Trade Commission (“FTC”), where I was project leader and principal author of the report jointly issued by the FTC and Department of Justice (“DOJ”), “Improving Health Care: A Dose of Competition” (2004). The report built on twenty-seven days of hearings held throughout 2003, and a two-day workshop held in 2002. While at the FTC, I worked on a number of other projects as well, including advocacy letters directed at bills being considered in Rhode Island (any willing pharmacy) and California (PBM transparency). I have been retained as an expert in cases involving pharmaceutical pricing, testifying on behalf of several state Medicaid programs.