

Government Regulation of Prescription Drug Pricing

The Academy of Managed Care Pharmacy (AMCP) believes that government regulation of prescription drug pricing, regardless of its structure, would have an overall negative impact on consumer cost, quality, and access to health care benefits. Regulated prices can cause cost-shifting to other consumers and may inadvertently discourage appropriate drug prescribing, dispensing and utilization.

The negative consequences of government intervention in the pharmaceutical marketplace have been illustrated by the best price provisions of the Medicaid prescription drug rebate program, which required manufacturers to provide large rebates to state Medicaid programs.¹ In response to the legislation, drug manufacturers attempted to recoup their lost profits in the government-regulated market by charging more to consumers in other unregulated markets and gradually raising prices to all markets over time. As a result, well-organized commercial purchasers such as health maintenance organizations (HMOs) and group purchasing organizations (GPOs), as well as public purchasers such as the Veterans' Administration (VA) and the Department of Defense (DOD), experienced price increases.² Drug cost increases could result in higher health insurance premiums, increased consumer co-pay or co-insurance requirements, and reduced or eliminated pharmacy benefits. Most importantly, employers and individuals may be forced to discontinue their health care insurance altogether, pushing consumers into public health programs (such as Medicaid or Medicare) or publically subsidized health insurance coverage options, increasing costs to taxpayers.

Government-regulated prices could greatly impair the ability of managed care organizations (MCOs) to design a competitive benefit offering that integrates clinically sound, evidence-based medication choices with delivery systems and co-payment alternatives that provide beneficiaries with substantive choice. MCOs have developed formulary systems alongside prudent purchasing practices to encourage appropriate drug prescribing, dispensing and utilization. As outlined in the consensus document *Principles of a Sound Drug Formulary System*³, formulary systems are complex structures that are dependent on a variety of components whose interactions result in patients having access to the medications they need in an affordable manner. Prescription drug prices which are regulated by the government would inappropriately separate therapeutic evaluations of a drug from cost-effectiveness considerations. For example, the government could mandate or negotiate a low price for a prescription drug which a MCO may have decided to leave off their formulary for safety reasons. If the product is publicly listed as the lowest-cost drug in its therapeutic class, however, MCOs may have no alternative but to add the medication to formulary based on public and government-driven demand. In therapeutic classes with multiple acceptable treatment alternatives, MCOs are also able to use formulary placement to move market share, giving the MCO leverage when negotiating price discounts with manufacturers. Government-regulated prices could eliminate the manufacturer's motivation to negotiate, resulting in increased costs and decreased quality of benefit coverage and services.⁴

Legislators may also be tempted to regulate prescription drug prices at the retail level. While legislation that would regulate retail-level drug prices, such as controlling the amount a pharmacy could charge a customer at the point-of-sale, may generate a short-term savings to the self-paying customer, it could result in fewer pharmacies staying in business, reduced competition among retail pharmacies and reduced access to pharmacy services. As the number of retail pharmacies increases, the remaining pharmacies will gain negotiating power, driving up the cost of services to MCOs.

Government regulation of prescription drug prices may also jeopardize the research and development of new pharmaceutical products. Government-regulated prices could dampen innovation due to costly research and development. Fewer pharmaceutical products could result in increased utilization of more costly and risky therapies, such as surgery and hospitalizations. The net result, again, could be an increase in costs and insurance premiums and a decrease in health care quality. In addition to the negative impact on the health care industry, reduced pharmaceutical research & development could impact our global balance of trade, since the U.S. is the world's major exporter of drugs, and could impact other related industries, such as agriculture and chemicals.

Past government intervention has resulted in increased pharmacy pricing for many consumers. Legislation that would allow the government to regulate prescription drug prices, though well intentioned, could actually result in increased costs for many consumers in the short term and for all in the long term. Government-regulated prices may ultimately increase the number of uninsured and decrease quality of care, exacerbating the very problem that these pricing laws are intended to solve.

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¹ Established by the Omnibus Reconciliation Act of 1990 (OBRA '90) (P.L. 101-508).

² See also AMCP's *Where We Stand on the Best Price Requirements of the Medicaid Rebate Program*, available online at www.amcp.org/positionstatements.

³ *Principles of a Sound Formulary System*, consensus document endorsed by AMCP, Alliance of Community Health Plans, American Medical Association, American Society of Health-Systems Pharmacists, Department of Veterans' Affairs, Pharmacy Benefits Management Strategic Healthcare Group, National Business Coalition on Health, U.S. Pharmacopeia (October 2000). Available online at: www.amcp.org.

⁴ See also AMCP's *Future of Medicare Part D: Reliance on Medicare Part D Plan Sponsors to Negotiate Prices with Pharmaceutical Manufacturers*, available online at <http://www.amcp.org/Sec.aspx?id=8620>, and AMCP's *Where We Stand on Formularies*, available online at www.amcp.org/positionstatements.