REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 2 - A-07

Subject: Maximum Allowable Cost of Prescription Medications (Resolution 103, A-06)

Presented by: William A. Dolan, MD, Chair

Referred to: Reference Committee A (Virginia E. Hall, MD, Chair)

At the 2006 Annual Meeting, the House of Delegates referred Resolution 103 to the Board of Trustees. Introduced by the American Association of Public Health Physicians, Resolution 103 (A-06) asked that the AMA "call for the development and regulation of a maximum allowable cost of each prescription medication sold in the US." The Board of Trustees assigned this item to the Council on Medical Service, for a report back to the House at the 2007 Annual Meeting.

Consistent with longstanding AMA policy (Policies H-180.978, H-330.898[5], H-330.938, and H-40.969[2], AMA Policy Database), the preponderance of testimony on Resolution 103 (A-06) at the House of Delegates stressed fundamental opposition to price controls of any kind. However, testimony also suggested that the implementation of Medicare Part D has raised questions about whether the Secretary of the Department of Health and Human Services (HHS) should be allowed to negotiate drug prices on behalf of Medicare beneficiaries. Accordingly, the Council reviewed previous work on controlling prescription drug costs, and examined information related to the way drug prices are being determined under Medicare Part D.

AMA POLICY

As noted above, various AMA policies oppose the use of price controls within the health care system. However, the AMA is committed to ensuring patient access to necessary drugs (Policy H-110.997), and has developed a comprehensive set of policies directed toward controlling prescription drug costs through other mechanisms. Several policies (Policies H-110.995, H-110.998, H-110.996, D-110.993, and D-110.997) stress the importance of urging the pharmaceutical industry itself to identify, develop, and implement market-based solutions to address those factors contributing to the rapid growth in pharmaceutical spending. Policies also call for the careful study of the true costs and benefits of prescription drug availability (Policies D-110.991 and D-110.995). Other policies emphasize the value of generic drugs in offering a lower-cost, therapeutically equivalent alternative to brand name drugs (Policies H-110.997, and H-125.984), and helping patients understand the true (i.e., before insurance) cost of prescription medications (Policy H-110.991).

At the 2004 Annual Meeting, the House of Delegates supported giving the Secretary of HHS the authority to negotiate contracts with manufacturers of drugs covered under Medicare Part D (Policy D-330.954). Yet, in response to the establishment of this policy, the Council raised the following concerns in its Report 3 (I-04):

> the challenge in these types of efforts [i.e., implementing pricing requirements and regulations] will be to ensure that the collateral effects of proposed legislation are carefully considered in advance of passage and program implementation. For example, at what point do "negotiated price reduction" programs become "price control" programs? What impact will such programs have on the safety, scope, and size of the current and future supplies of prescription drugs? Will these programs actually reduce overall prescription drug prices, or will they serve mainly to encourage parties of prescription drug transactions to simply shift costs among themselves? Will there be any unintended, adverse affects of such programs on vulnerable patient populations? As previously noted, any potential policy reform that does not explicitly account for these interactions may or may not produce the desired outcome and, furthermore, may result in unintended consequences.

RELEVANT REPORTS OF THE COUNCIL ON MEDICAL SERVICE

Over the past several years, the Council has presented three reports that specifically address the rise in prescription drug costs. Council on Medical Service Report 3 (A-00) responded to a directive from the House of Delegates to undertake a comprehensive study of "the problem of increasing pharmaceutical costs." That report concluded that there are several factors driving the increase in drug costs, and that a combination of methods will be needed to address the problem. Although not an explicit focus of the report, the Council cited existing AMA policy (e.g., Policy H-330.898[5]), which strongly rejects the use of price controls because of their potential to "stifle innovation and increase utilization."

Council on Medical Service Report 2 (A-02) responded to a House directive to study the effects of various state actions to control pharmaceutical costs. The informational report examined the use of strategies such as pharmaceutical discount and rebate programs, and group purchasing cooperatives, and cited efforts in Maine to use the threat of price controls to help keep drug prices low. On the subject of price controls, Council Report 2 (A-02) noted:

> The AMA has long-standing policy opposed to price controls on health care expenditures. Pharmaceutical companies oppose price controls because of a variety of adverse effects they have for industry income. In Europe, pharmaceutical price controls are a common means of controlling health care spending, and drug companies have recently suggested they may divert their investment and research dollars from Europe to the US market. The impact of European pharmaceutical price controls not only results in direct loss of income for pharmaceutical companies, but in the creation of drug markets whereby wholesalers purchase drugs in countries with the stiffest price controls and sell them in countries where drug prices are higher. The drug companies then lose sales in those countries where price controls are smaller or nonexistent, while demand for drugs is inflated in those countries with artificially controlled prices.

Finally, Council on Medical Service Report 3 (I-04) responded to two resolutions that asked the AMA to consider ways to reduce prescription drug prices, including the use of price controls. The report concluded that:

> Given the AMA's long-standing policy in support of pluralism and free market competition, and in opposition to price controls, the Council believes that there is merit in continuing to encourage the pharmaceutical industry to exercise reasonable restraint in the

> pricing of prescription drugs, and to support programs whose purpose is to contain the rising costs of prescription drugs, provided that such programs adhere to AMA principles.

RECENT ACTIVITY RELATED TO MEDICARE PART D

As noted in the Whereas clauses of Resolution 103 (A-06), and in testimony during Reference Committee A at the 2006 Annual Meeting, the availability of prescription drug coverage under Medicare Part D has generated extensive discussion about the best way to control drug costs so that they do not impose an extraordinary burden on beneficiaries or the already fiscally strained Medicare program. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) emphasizes the role of private plans and market competition in restraining drug prices, and explicitly forbids the government from interfering in drug price negotiations between drug manufacturers and the Medicare drug plan sponsors, and from defining any specific pricing structure for pharmaceuticals (the "noninterference clause").

There is some concern that the noninterference clause prevents Medicare from obtaining the lowest possible price for pharmaceuticals. Many feel that as the largest single purchaser of prescription drugs, the Medicare program (through the Secretary of HHS) should be able to negotiate directly with drug manufacturers to secure the lowest price. Several members of Congress have been advocating to overturn the noninterference clause and, in January 2007, the US House of Representatives passed H.R. 4, which would require the Secretary of HHS to negotiate drug prices with manufacturers, but prohibits the Secretary from requiring a particular formulary.

The Congressional Budget Office's (CBO) analysis of H.R. 4 "estimates that H.R. 4 would have a negligible effect on federal spending because we anticipate that the Secretary would be unable to negotiate prices across the broad range of covered Part D drugs that are more favorable than those obtained by PDPs [prescription drug plans] under current law." The analysis also notes that the inability to negotiate formulary structures (which PDPs are currently able to do, subject to certain limits) would severely limit HHS' negotiating position, since formulary design is one of the key elements on which price negotiations are based. Finally, CBO notes that "PDPs also bear substantial financial risk and therefore have strong incentives to negotiate price discounts in order to control their costs and offer coverage that attracts enrollees through features such as low premiums and cost sharing requirements."

Similarly, the Congressional Research Service issued a report in January 2007 entitled, "Federal Drug Price Negotiation: Implications for Medicare Part D." That report concludes that,

> If the Secretary [of the Department of Health and Human Services] were to engage in activities that affect drug prices on behalf of Medicare Part D beneficiaries, there might be consequences that affect the price of drugs for Medicare beneficiaries as well as other public and private patients, the number and types of drugs that would be available to Part D beneficiaries, the amount of research and development and innovation by pharmaceutical companies, and other sectors of the industry.

As previously noted, AMA Policy D-330.954 supports giving the Secretary of HHS the authority to negotiate contracts with manufacturers of drugs covered under Medicare Part D. However, since D-330.954 was adopted (in 2004, prior to implementation of Part D), there has been substantial evidence to suggest that the price negotiations being conducted at the individual plan level by PDPs

already result in significant cost savings. Cost projections for Medicare Part D have continually been revised downward, and beneficiary premiums are significantly lower than originally projected. According to data from the Centers for Medicare and Medicaid Services (CMS), beneficiaries are saving an average of $1,200 per year, and in 2007 the average monthly Part D premium will be 42% lower than originally estimated. CMS actuaries also project that payment to Part D plans will be $113 billion lower over the next ten years, with approximately $96 billion of the savings a direct result of competition and lower bids submitted by Part D plans. As suggested in the CBO analysis, the market expertise of PDPs, along with the incentives for the plans to compete with one another for beneficiary enrollments, appears to result in an efficient and effective negotiation process.

DISCUSSION

Although the escalation of prescription drug costs is a matter of concern for physicians and patients, the House of Delegates has continually reaffirmed and reinforced AMA policy opposing price controls and supporting the use of market-based mechanisms to manage health care costs. Despite initial concern over the noninterference clause in the MMA, experience over the past year with Medicare Part D has demonstrated that decentralized price negotiations conducted by PDPs with industry expertise have resulted in significant savings to beneficiaries and the federal government. In response to recent Congressional calls to grant the Secretary of HHS the ability to negotiate drug prices, the Congressional Budget Office and the Congressional Research Service have both indicated that it is unlikely that such negotiation, as currently proposed, would yield greater cost savings, and could even undermine efforts to keep drug prices low for seniors.

Although Resolution 103 (A-06) addresses drug costs for all prescription drugs in the US, the Council believes that the debate surrounding the ability of Medicare Part D to control drug costs provides strong evidence to suggest that leveraging market forces is a more effective way of controlling drug costs than imposing price limits or centralizing negotiating authority. While several AMA policies refer to AMA opposition to price controls, the Council believes it would be useful to establish a stand-alone policy statement that captures the overall strategy of the AMA regarding market-based health system reform.

RECOMMENDATION

The Council on Medical Service recommends that the following be adopted in lieu of Resolution 103 (A-06), and the remainder of the report be filed:

> That our American Medical Association (AMA) oppose the use of price controls in any segment of the health care industry, and continue to promote market-based strategies to achieve access to and affordability of health care goods and services. (New HOD Policy)

References for this report are available from the AMA Division of Socioeconomic Policy Development.

Fiscal Note: No Significant Fiscal Impact