



Medicines and markets: the USA and Australia

Ruth Lopert, Principal Medical Adviser, Therapeutic Goods Administration, Canberra

Key words: drug costs, drug therapy, Pharmaceutical Benefits Scheme.

(Aust Prescr 2009;32:90–1)

Among developed countries, the USA is virtually alone in its reluctance to intervene in response to market failure in pharmaceuticals. It was not until the introduction of the US Medicare Part D drug benefit in 2006 that millions of elderly and disabled Americans gained access to subsidised prescription drugs. After 40 years without any drug coverage, this controversial expansion of the Medicare program has been hailed as a triumph. It has also been described as complex, expensive and lacking in transparency.

Under Part D, benefits are provided through private insurance policies sold in federally-defined regional markets. Eligible enrollees (over 65s and the disabled) pay monthly premiums to participate in the drug plan of their choice. They may choose either a stand-alone drug plan (known as a PDP) or a managed care plan with integrated drug coverage (known as a Medicare Advantage PDP or MA-PDP), from a list of several dozen of each in any given region. Under Part D, the federal government contributes approximately 75% of the premium costs.¹

Most Part D plans have tiered benefit structures, in which co-payments are varied to encourage patients towards the cheapest options. Plans typically have four tiers, with the first tier comprising generics, the second 'preferred brands', and the third 'non-preferred brands'. Plans may also place any drug costing \$600* or more per month into a so-called specialty tier, and will usually apply a co-payment (or strictly speaking a co-insurance amount) of 25–33% of the drug price. Plan providers are largely free to determine which drugs are on their formularies (with the exception of drugs in certain 'protected' classes for which coverage is mandatory) and in which tiers those drugs are placed. They may also move drugs between tiers, or drop coverage of a drug during the plan year. In contrast, enrollees may switch plans only during a six-week 'open enrolment' window each November.¹

In 2009 Part D premiums average \$30.36 per month, but vary significantly across plans and regions, ranging from \$10.30 to \$136.80. This year under the standard benefit, enrollees face an annual excess of \$295, after which 75% of their drug costs are covered, but only up to \$2700. Once they have spent \$4350

out-of-pocket in a calendar year (or a total of \$6154 in drug costs), 95% of their costs are covered (the catastrophic coverage zone). Between \$2700 and \$4350 is the infamous 'doughnut hole' where enrollees are liable for 100% of their drug costs, even as they continue to pay their monthly premiums. These thresholds are indexed annually in accordance with Part D spending growth.¹

In 2007, the 24.2 million Part D enrollees spent on average \$461 out-of-pocket on prescription drugs, in addition to their monthly premiums. Fourteen percent fell into the doughnut hole; of these, about one-third were aged 85 or older and 15% stopped taking their medications as a result. For those who qualified for catastrophic coverage, average monthly out-of-pocket costs were still \$285.²

Importantly, in designing Part D, Congress deliberately chose not to intervene in the pricing process and legislated to prohibit government intervention in drug price negotiations. Individual plan providers must each contract with drug companies to obtain discounts and rebates in return for favourable placement of their drugs on plan formularies. However, providers' capacity to negotiate is to some degree constrained, particularly for those drugs for which inclusion on plan formularies is mandatory. Consequently, Part D prices are high in comparison with Medicaid and other federally funded programs (which all have statutorily mandated discounts or rebates). In some cases prices are scarcely lower than retail.^{3,4,5} In addition to concerns over high prices, the complexity of benefit structures, and the generous protections offered to induce the private sector to enter the Part D market, the program has been heavily criticised for its lack of transparency. Until recently there has been a dearth of data that would allow any formal scrutiny of its performance.^{6,7}

The Obama administration faces unprecedented health policy challenges, with healthcare spending projected to reach \$3.1 trillion in 2012, and rising unemployment likely to swell the ranks of the 47 million people currently uninsured (and the many underinsured).^{8,9} The President has signalled lowering drug prices as a priority and has proposed legalising parallel importation of medicines from Canada and other countries with administered pricing systems, as well as increasing the use of generic medicines. Repealing the prohibition on direct price negotiation by government under Part D has also been mooted, but how negotiations would be undertaken, and for what, is

* All costs are expressed in US dollars

unclear. Without a formulary and a rational decision-making framework with the capacity to limit the use of or exclude a drug, it is difficult to see how savings could be achieved. Currently there is growing support in the US for the establishment of mechanisms to evaluate the comparative effectiveness of medical treatments, but there is little enthusiasm for evaluating their comparative cost-effectiveness. Taking into account costs when comparing treatments is widely disparaged as being 'not about medical discovery, but about bean counting'.¹⁰

In Australia there is at times frustration with the listing recommendations of the Pharmaceutical Benefits Advisory Committee, the time taken for drugs to be listed on the Pharmaceutical Benefits Scheme (PBS), the price of listed medicines, and the magnitude of out-of-pocket costs. While it is tempting to try to contrast Part D with the PBS, the heterogeneity of Part D makes assessments of the breadth and comprehensiveness of plan formularies and the metrics of costs, coverage and access particularly complex. Some Part D formularies may well be more extensive in the drugs they cover than the PBS, but the permutations arising from tiered benefit structures, variable cost sharing, and movements of drugs on and off the formularies and between tiers make it extremely difficult to determine the significance of the differences. Certainly Part D offers a great deal of choice for enrollees, but rather than conferring a sense of control, the nature and breadth of the choices offered has created complexity and confusion for many elderly and disabled Americans. Part D is arguably an example of a phenomenon that seems to be widespread in US health care – the design of the policy prioritises the act of choosing rather than the utility of the choice. Despite the emphasis on choice, enrollees cannot choose to have a stable benefit with constant coverage throughout the year.

By contrast, the PBS offers less choice, but is arguably simpler for both patients and prescribers, more equitable, and more transparent. It has a uniform national formulary, accessible information about prices and standard co-payments. Decision making is based on evidence of comparative effectiveness and comparative cost-effectiveness. This not only helps to determine the opportunity costs of new treatments, but also ensures value for money for the taxpayer and the healthcare system. It will be fascinating to see whether the imperative to rein in US healthcare expenditure will ever see Part D, or for that matter US Medicare, adopt a similar model.

Postscript

On 20 June 2009 the Pharmaceutical Research and Manufacturers of America announced its support for a plan to provide discounts of 50% to 'most beneficiaries on brand-name medicines' purchased in the Part D doughnut hole.¹¹ Although worth up to \$80 billion over 10 years, some of the revenue foregone will nevertheless be recouped through increased sales of brand-name drugs to enrollees who would otherwise

switch to generics in the doughnut hole. It may also be intended to lessen the impetus for introducing government drug price negotiations. While reported to have strong support from the President, the program will not help offset the cost of healthcare reform, as discounts will reduce out-of-pocket costs to enrollees but deliver no savings to government. These most significant changes to Medicare Part D could be argued as evidence that the program is failing to provide consumers with affordable drug coverage.

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Conflict of interest: none declared