IN ANY DISCUSSION of key pharmaceutical policy issues, Australia's National Medicines Policy (NMP) is an important touchstone of which Australians can be justly proud. Those familiar with the stalled evolution of the Canadian National Pharmaceuticals Strategy and the uneven provincial patchwork of pharmaceutical coverage in Canada for example, may wonder why it is that a country with longstanding universal health care has neither universal coverage of medicines nor a cohesive national policy framework like Australia's NMP.

One of the fundamental objectives of the NMP is to deliver "timely access to the medicines that Australians need, at a cost individuals and the community can afford". It also says that "cost should not constitute a substantial barrier to people's access to medicines they need" and that while "...the Pharmaceutical Benefits Scheme (PBS) facilitates access to certain prescribed medicines by subsidising costs ... (S)uch subsidies are not costless, and the community as a whole must bear them". Importantly it also says that "...access to medicines should support the rational use of those medicines".1

These extracts from the NMP lie at the kernel of the two papers in this issue of the Journal that discuss PBS copayment policy. Doran and Robertson focus on the role of moral hazard in copayment policy and argue that it is ingrained in, and fundamental to, the policy thinking around the PBS.2 Sweeny considers the impact and implications of increasing copayments and the safety net threshold.3

Whether the concept of moral hazard is a policy canon or simply an interpretation of current cost sharing policies is perhaps of academic interest. The key issue is surely whether any disincentives to inappropriate use do not also preclude or discourage appropriate use. Moreover if a fundamental belief in moral hazard is at the heart of policymaking then there is arguably a policy discontinuity within a health care system which encourages primary care practitioners to bulk-bill their patients (and still receive 100% of the scheduled fee).

Setting aside the concept of moral hazard as a driver of copayment policy for the moment, is it unreasonable that individuals should contribute to the cost of their medicines? If not, then once again the key issue is surely “How much, and how much is too much?” At the heart of both papers is an argument that copayments are about cost shifting, and as a result increasing costs are deterring patients from having prescriptions filled, thus reducing or negating the benefit of prescription medicines, and inducing a net reduction in patient (and societal) welfare. In particular, Sweeny argues that for the most part, where copayments and safety net thresholds are only adjusted for inflation, but incomes rise faster then inflation, this gives rise to a situation where one-off adjustments lead to welfare-reducing abstinence.

As an aside, it is interesting, when considering these issues, to look at some overseas examples. At £6.50 the general copayment in the United Kingdom is significantly lower than the PBS general copayment, and by virtue of a series of exemptions around 80% of Britons pay no copayments at all. Moreover, on 23 September 2008,
the British Prime Minister announced that the government would abolish prescription charges for cancer patients from April 2009 and that over the next few years, charges for patients with long-term conditions would also be phased out. In this case it is not clear whether this is a policy driven by compassion, or the concept of value-based benefit design, or both. Prescription charges have also been completely phased out in Wales and are in the process of being phased out in Scotland. At the other end of the spectrum are United States Medicare beneficiaries (over 65s and disabled), who with the establishment of Medicare Part D gained access to drug coverage for the first time in 2006, 40 years after the establishment of Medicare itself. One of the most striking features of Part D — apart from a complex and convoluted benefit structure — is the magnitude of patient copayment and coinsurance amounts, which apply over and above monthly Part D premiums (which for most beneficiaries would already exceed the PBS concessional safety net amount). Under the standard benefit, covered benefits are payable at a rate of 75 percent up to an expenditure threshold; at this point, enrollees fall into what is known as a “doughnut hole” and must incur thousands of dollars in costs until they reach a second, “catastrophic” threshold, at which point, plan coverage resumes, with payment of 95 percent of costs. The value of both the subsidy and the doughnut hole are pegged to an annual inflation rate. Baskets of drugs commonly prescribed in the elderly — and for which costs would be capped at around $300 under the PBS — will typically command thousands of dollars in copayments under Part D. Yet despite these massive patient contributions there is widespread support for the new benefit among beneficiaries.

This then provides an interesting counterpoint to the perspective that Australian copayments and safety nets are unreasonable. Both papers argue that there is persuasive evidence that the costs of medicines borne by Australian consumers today are unreasonable and that this not only violates one of the explicit objectives of the NMP but also imposes the very “substantial barrier to people's access” that the NMP eschews. This is supported by the recent analysis by Hynd and colleagues that showed that following the large January 2005 increase in PBS copayments, significant decreases in dispensing volumes were observed in a large number of medicines, particularly those used for asymptomatic conditions and by concessional beneficiaries. But are these changes in behaviour analogous to a kind of “sticker shock” that will lessen over time as consumers adjust to the new levels? Are perceptions of the affordability of patient contributions conditioned to some degree by what consumers are accustomed to paying, as the experience of Medicare Part D might suggest?

Sweeny also argues that recent policy changes made to the PBS have been aimed not just at cutting the absolute costs of the PBS to government, but also at reducing the proportion of the PBS contributed by government. The data suggest otherwise however; in fact the proportion of the PBS contributed by government has not varied substantially over the last 17 years, and despite the substantial adjustment in 2005 has since returned to the previous level of around 85% of overall expenditure (calculated from Department of Health and Ageing data).

Of course averages are never the whole story. Out-of-pocket costs borne by general beneficiaries include under-copayment prescriptions, and many of these will only be marginally lower than the general copayment. Moreover, the price cuts to many off-patent medicines arising from the measures introduced under PBS reform will push more and more products below the general copayment. Unfortunately there are currently no data available on out-of-pocket expenditure on scripts attracting less than the general copayment. Since these prescriptions attract no contribution from the Commonwealth, and reimbursements to pharmacies are based on claims made to Medicare Australia, only the Pharmacy Guild can know how much is really being spent. It would seem though, that any reasoned debate about the

*These findings may however be confounded to some degree by the simultaneous introduction of the Safety Net 20 Day Rule, on 1 January 2006.
impact of copayments to consumer affordability cannot be had without taking this expenditure into account.

Another way of looking at this question might be whether it is reasonable for patients or consumers to contribute to the costs of their care, and therefore, whether having separate safety net arrangements for PBS and MBS (Medicare Benefits Schedule) continues to be sensible construct. Should medicines be treated differently from other treatment modalities? Unfortunately the current MBS and PBS policy frameworks do not lend themselves easily to establishing a mechanism to pool contributions and safety nets. Medicine prices (for subsidy purposes) are effectively capped by the PBS, whereas the prices of medical services and procedures are not (except of course where they are bulk-billed). This of course renders the calculation of a combined safety net arrangement a truly wicked problem. Conceptually though, an argument can be mounted for no longer allowing these to be siloed as they are currently.

Should copayments differ according to the seriousness of a disease, the cost of the drug, the capacity to pay, or the capacity to benefit? Sweeney argues that the government should shift from its “... well articulated policy for pricing PBS medicines ... developed and tested over a considerable period of time ... (to) a similar policy for setting the levels of copayments and [safety net thresholds]”. He suggests maintaining the real value of both as a constant proportion of either inflation or of average household incomes. This could be applied to the purchase of all PBS medicines or to those medicines which are necessary to treat life-threatening or incapacitating disease. Doran and Robertson suggest exploring elements of value-based benefit design (VBBD) as an alternative to the current policy structure. VBBD incorporates financial incentives into prescription drug or other insurance benefits to encourage initiation of, and adherence to, treatment regimens (especially primary or secondary preventive regimens) where higher utilisation levels yield clinical benefits that generate downstream cost savings elsewhere in the health care budget. The types of financial incentives that have been suggested include the reduction or complete elimination of cost sharing, as well as incentives or rewards for high levels of adherence. VBBD can be applied universally — in other words, to all patients for whom a drug might be indicated — or selectively to targeted subgroups of patients most likely to benefit clinically or to respond more readily to benefit design incentives. The greater the ability to target the incentive, the larger the cost savings to the payer. A key question in any discussion of VBBD would of course be whether policy settings which command different copayments from different patients are compatible with the implied equity objective of the NMP. Of course the same question might be raised apropos under copayment scripts.

Many questions, few easy answers. One thing is clear however. Copayment policy will always be contested and uneasy policy-making space. And as the PBS segues into its seventh decade at a time of unprecedented global financial crisis, the imperative for fiscal belt tightening will no doubt render this space even more contested. Let’s hope the new National Medicines Policy Executive and Committee can offer some insight, clarity and direction for the future.

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Competing interests
The author declares that she has no competing interests.

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