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## Health and Ageing Legislation Amendment Bill 2003

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I N F O R M A T I O N   A N D   R E S E A R C H   S E R V I C E S

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Health and Ageing Legislation Amendment Bill 2003

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14 May 2003

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# Health and Ageing Legislation Amendment Bill 2003

**Date Introduced:** 27 March 2003

**House:** Senate

**Portfolio:** Health and Ageing

**Commencement:**

- **Schedules 1, 3 and 4** commence on Royal Assent.
- **Schedule 2** commences 28 days after Royal Assent.
- The items in **Schedule 5** commence on various dates.

## Purpose

To:

- Amend the *National Health Act 1953* to increase the number of members on the Pharmaceutical Benefits Advisory Committee; and make other changes to pharmaceutical supply arrangements.
- Make other changes to the National Health Act and related legislation in the Health and Ageing portfolio.

## Background

### Pharmaceutical Benefits Advisory Committee membership

The Pharmaceutical Benefits Advisory Committee ('**PBAC**') is an independent statutory body established on 12 May 1954 under section 101 of the National Health Act to make recommendations and give advice to the Minister about which drugs and medicinal preparations should be made available as pharmaceutical benefits. No new drug may be made available as a pharmaceutical benefit unless the Committee has so recommended.

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The Committee is required by the Act to consider the effectiveness and cost of a proposed benefit compared to alternative therapies. In making its recommendations the Committee, on the basis of community usage, recommends maximum quantities and repeats and may also recommend restrictions as to where PBS subsidy is available. When recommending listings, the Committee provides advice to the Pharmaceutical Benefits Pricing Authority regarding comparison with alternatives or their cost effectiveness.

The PBAC currently has a total membership of twelve, and currently must include eight members selected from the following six interests or professions: consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists, and medical specialists. At least one member must be selected from each of these groups.<sup>1</sup> The remaining four members (a third of the PBAC membership) are appointed by the Minister subject to them having qualifications and experience in a field related to the functions of the PBAC that allow them to contribute meaningfully to its deliberations.<sup>2</sup> The current amendments provide for PBAC membership to be increased by up to four people. The membership will consist of a chairperson with not less than eleven and not more than fifteen members. The amendments also provide that not less than two-thirds of the total number of members be selected from nominations of the prescribed external organisations. This maintains the current ratio between the number of members selected from nominations of external groups, and the number of members appointed by the Minister.

The proposed increase in the PBAC membership is intended to address the currently substantially increased workload of the medical specialists on the committee. The drugs and medicines put forward to the PBAC for listing are increasingly complex and specialised in their intended operation. The supporting clinical information submitted by manufacturers also tends to be lengthy. The adequate assessment of these new medicines for listing consequently calls for detailed scrutiny by professionals who have specialist expertise in different areas of medicine. There has also been considerable ongoing concern on the part of the pharmaceutical manufacturing industry about the delays involved in the assessment process for drugs submitted for listing. Also, there has been some industry concern at what has been described as a “lack of transparency” at how drugs are listed.<sup>3</sup> Although it is not the intention of the proposed increase in PBAC membership to address these industry concerns, it will increase the resources the PBAC has available to expedite applications and communicate its subsequent decisions.

## **Special Supply Arrangements**

Section 100 of the National Health Act enables certain specialised drugs and medicines which are not normally available through GPs or pharmacies to still be supplied as pharmaceutical benefits under certain conditions. Special supply arrangements might apply, for instance, in the case of highly specialised drugs for treatment of hospital in-patients with specific conditions. The Bill proposes to amend section 100 to clarify that these special supply arrangements can be used for the funding of particular medicines that

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are not available through the normal operation of the Pharmaceutical Benefits Scheme ('PBS').

### **Pharmacists Supplying Benefits from as yet Unapproved Premises**

Pharmaceutical benefits can only be supplied (and pharmacists reimbursed) for drugs and medicines supplied at approved premises. If a pharmacist relocates premises which are not as yet approved for the supply of pharmaceutical benefits, the pharmacist currently needs to proceed under the act of grace provisions in order to be reimbursed for the supply of medicines under PBS subsidy. Part 3 of Schedule 1 of the Bill proposes to amend the National Health Act to allow a pharmacist to supply medicines under subsidy while approval is pending, and obtain the reimbursement once approval is granted.

### **Supply of PBS medicines in approved hospitals**

New arrangements have been introduced with some States for the supply of pharmaceutical benefits to hospital out-patients, day admitted patients and admitted patients on discharge. This amendment will ensure that the forms and quantities of the medicines supplied under PBS subsidy from hospitals will conform to the specifications in the *Schedule of Pharmaceutical Benefits*, which currently apply to pharmacists and medical practitioners.

### **Cancellation of Approvals**

Section 98 of the National Health Act provides the Secretary or Minister with the power to cancel approvals to supply pharmaceutical benefits. The Bill proposes to amend section 98 to clarify that the Secretary or Minister has the discretion whether to cancel approval or not. Currently under the Act, the Secretary or Minister may be obliged to cancel an approval in cases where this may not be appropriate (for example, where a pharmacist has temporarily ceased to trade due to illness).

### **Simplified Health Insurance Commission billing arrangements**

Schedule 2 of the Bill proposes amendments to remove an anomaly in relation to “gap cover” insurance. The Medicare rebate covers 75% of the Medical Benefits Schedule fee for in-hospital medical expenses while private health insurance, through a Registered Health Benefits Organisation ('RHBO'), covers the remaining 25% of the MBS fee. Some medical practitioners charge a fee that is more than the scheduled MBS fee, and there is consequently a “gap” between the charged fee and the MBS fee. Some RHBOs provide insurance to cover such gaps, sometimes under Medical Purchaser-Provider Agreements with specific service providers. Currently, legislation requires that if a service is provided as part of a Medical Purchaser-Provider Agreement, the provider of medical services must

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forward all accounts to the RHBO, otherwise the RHBO is prevented from paying benefits to the patient in excess of 25% of the MBS fee. In other words, they are prevented from paying any “gap” benefit. This does not apply in the case of gap cover arrangements not under a Medical Purchaser-Provider Agreement.

This can disadvantage patients in some cases where practitioners prefer to give accounts directly to RHBO members, to forward on to their RHBO. If the member is not aware of the requirements that apply in the case of Medical Purchaser Provider arrangements, and claims the Medicare rebate prior to lodging the claim with the RHBO, then the member will not receive any gap benefit and will be left with an out-of-pocket expense. The proposed amendment would require the medical practitioner to send the account directly to the Health Insurance Commission rather than the RHBO. Accounts would be submitted electronically, in conformity with the HIC’s “electronic medical claiming model” and the Government’s “On-Line Strategy”.

### **Restoring Specialist Recognition**

An unintended consequence of the *Health Legislation Amendment Act (No 2) 2001* was that a number of medical specialists who were recognised prior to June 2001 as specialists for the purposes of the *Health Insurance Act 1973* were no longer recognised as specialists, and could not access Medicare benefits at the specialist rebate level. Schedule 3 of the Bill proposes amendments to the *Health Insurance Act 1973* to restore that status, and access to specialist level Medicare benefits.

### **Medicare Benefits and Overseas Doctors**

Currently, overseas trained doctors must commit to provide services in districts of workforce shortage if they wish to access Medicare. This reflects the Government’s policy regarding the maldistribution of the medical workforce, and the difficulties experienced by some rural communities in accessing general practitioner services. Schedule 4 of the Bill proposes amendments to the Health Insurance Act to enable overseas doctors who are accessing a bona fide training program and have a occupational trainee visa to claim Medicare benefits when they assist at operations as part of their training programs. This will facilitate the exchange of medical knowledge between Australia and overseas.

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## Main Provisions

The Bill proposes the following changes relating to the Pharmaceutical Benefits Scheme and pharmaceutical supply arrangements.

### Schedule 1

**Part 1** amends **section 100A** of the National Health Act by increasing the maximum number of PBAC members, including the Chairman, from 12 to 16. At least two-thirds of the members must be selected from six different professional groups, with the remaining members appointed by the Minister. The current requirement for at least one member from each professional group is maintained. PBAC is to have at least 12 members, but can function for periods of up to six months with lesser numbers.

**Part 2** amends **section 100** of the National Health Act to clarify the conditions under which special supply arrangements can be used for the funding of particular medicines that are not available through the normal operation of the Pharmaceutical Benefits Scheme. On the recommendation of PBAC, the Minister can declare a 'drug or medicinal preparation' to be a 'special pharmaceutical product' for the purpose of such funding. Such declarations – and any variations or revocations – are deemed to be 'disallowable instruments' and must be tabled in Parliament within 15 sitting days.

**Part 3** amends **subsection 99(3)** of the National Health Act. The new provision assists pharmacists who do not obtain the necessary prior approval to supply benefits from a new location. Once approval is obtained, the pharmacist will be entitled to a payment of 90% of the pharmaceutical benefits supplied from the new location.

**Part 4** amends **sections 84DA and 84E** of the National Health Act to allow an agent to make and sign an application for a PBS safety-net or concession card where the applicant is unable to sign the application.

**Part 5** repeals **subsection 94(6)** of the National Health Act to ensure that determinations of the forms, strengths and brands of PBS medicines and their maximum quantities and repeats will apply to the supply of pharmaceutical benefits by hospitals in the same way as they do to pharmaceutical benefits supplied by pharmacies.

**Part 6** amends various subsections in **sections 98 and 98AA** of the National Health Act to make it clear that the decision-maker (be it the Secretary or the Minister) has the discretion whether or not to cancel an approval for the supply of pharmaceutical benefits.

**Schedule 1** commences on Royal Assent.

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## Other Schedules

**Schedule 2** amends section 73BDA of the National Health Act allowing medical providers to forward account claims to the Health Insurance Commission instead of a health fund. The Explanatory Memorandum notes that this will allow 'a consolidated payment incorporating both Medicare and private insurance benefits to be made to the provider of medical services'.<sup>4</sup> **Schedule 2** commences 28 days after Royal Assent.

**Schedule 3** amends the *Health Insurance Act 1973* to restore specialist recognition status for the purpose of ensuring access to Medicare benefits at the specialist rebate level. **Schedule 3** commences on Royal Assent.

**Schedule 4** amends subsection 19AB(7) of the Health Insurance Act to ensure that no Medicare benefit will be payable for the professional services of an overseas trained doctor who assists at an operation unless the doctor is the holder of an exemption granted under the Act. **Schedule 4** commences on Royal Assent.

**Schedule 5** makes minor technical amendments to the *Aged Care Act 1997* and the Health Insurance Act. The items in **Schedule 5** commence on various dates.

## Concluding Comments

### Pharmaceutical Benefits Advisory Committee membership

It should be noted that neither the Act nor the related regulations specify that the four new members of the PBAC must be medical specialists, nor chosen from any particular categories of the six specified in the regulations. Also, only three of the four new positions need to be selected from professional and consumer group nominations, and one new member selected by the Minister.<sup>5</sup> The Minister, however, must still select members whose qualifications and experience satisfy the Minister that they can contribute meaningfully to the deliberations of the committee. The conditions under which the Minister can select members remains the same, even if the number of members the Minister can select under those conditions has increased.<sup>6</sup>

The proposal that two-thirds of the PBAC membership be selected from external bodies and one third by the Minister, may be subject to interpretation.<sup>7</sup> If this applies only to the *initial selection* of PBAC members, then there is no obvious requirement to *maintain* that proportion where members leave or are removed (permanently or temporarily) from the PBAC without being replaced. In this case, circumstances might arise over time where the Ministerial representation on the PBAC becomes greater than one-third, or alternatively, the external representation greater than two-thirds. Moreover, circumstances may arise during a six month period, where the Ministerial representation on the PBAC exceeds that of externally nominated members.<sup>8</sup> This would not arise if the amended subsection

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100A(3) made it clear that the membership ratio of two-thirds to one third were to be maintained throughout possible changes in the number of committee members.

## Endnotes

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- 1 The members selected from these groups are appointed by the Minister from nominations made by specific community bodies and professional associations named in the regulations related to the Act. Each of these bodies or associations must nominate at least three people.
- 2 Prior to December 2000, only the AMA could make recommendations to the Minister for vacancies on the PBAC. A review group convened by the then Parliamentary Secretary for Health Senator Grant Tambling recommended that PBAC members should come from a broader range of constituencies, and this recommendation was enacted in the *National Health Amendment (Improved Monitoring of Entitlements to Pharmaceutical Benefits) Act 2000*.
- 3 It has been suggested that delays and lack of transparency will adversely affect pharmaceutical industry research and development in Australia. See “Drug giant warns PBS delays will cost millions”, *Australian Financial Review*, 24 April 2003.
- 4 Explanatory Memorandum p. 9.
- 5 Under the proposed amendments, eleven of the maximum of sixteen PBAC members would need to be chosen from external nominations (only three more than the current eight).
- 6 Under the existing provisions, the Minister can select at most four (out of twelve) members. Under the proposed amendments, the Minister can select at most five (out of sixteen) members.
- 7 Proposed amendment to subsection 100A(3)
- 8 The proposed amendment to subsection 100B(3) enables the PBAC to perform its functions and exercise its powers with fewer than twelve members for a period of no more than six months.

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