



## National Health Amendment (Pharmaceutical Benefits) Bill 2007

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## National Health Amendment (Pharmaceutical Benefits) Bill 2007

**Date introduced:** 15 August 2007

**House:** Senate

**Portfolio:** Health and Ageing

**Commencement:** On Royal Assent or the day after, except for four items which commence on 1 January 2008

**Links:** The [relevant links](#) to the Bill, Explanatory Memorandum and second reading speech can be accessed via BillsNet, which is at <http://www.aph.gov.au/bills/>. When Bills have been passed they can be found at ComLaw, which is at <http://www.comlaw.gov.au/>.

### Purpose

- to enable optometrists to prescribe subsidised medicines under the Pharmaceutical Benefits Scheme (PBS)
- to restrict pharmacists who wish to supply medicines under the PBS from supplying only by mail order

### Background

#### Prescribing rights for optometrists

The Commonwealth Government has been subsidising medicines to Australians since 1948,<sup>1</sup> and currently does so through the PBS under the *National Health Act 1953* (the Act). Total expenditure on the PBS was over \$6.4 billion last year.<sup>2</sup> The PBS was extended to enable dentists to prescribe medicines in 1978.<sup>3</sup>

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1. Most of the *Pharmaceutical Benefits Act 1947* came into operation on 1 June 1948. An earlier Act, the *Pharmaceutical Benefits Act 1944*, was invalidated by the High Court and was never proclaimed to come into effect.
  2. Budget 2007–08, Portfolio Budget Statements, [Health and Ageing Portfolio](#), p. 73.
  3. *National Health Amendment Act (No. 2) 1978*.

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*Consultations* with optometrists have been subsidised under Medibank or its successor Medicare since 1975.<sup>4</sup> Under current arrangements, however, patients who need eye medicines are obliged to follow a visit to an optometrist with a visit to a GP for a prescription, if they wish to receive subsidised medicine under the PBS.

The states and territories have implemented changes to the prescribing rights of optometrists over a number of years. Victoria passed legislation in 1995, Tasmania in 1996 and New South Wales in 2002. The ACT began to address the issue with a discussion paper in September 2003, following a request from the professional bodies in June 2002.<sup>5</sup> ACT legislation was changed in 2005.<sup>6</sup> Queensland announced changes in 2003, and made regulations in 2005.<sup>7</sup> The Northern Territory was also considering changes in 2003, and passed legislation in December 2006.<sup>8</sup> In May 2005 it was reported that optometrists were undergoing training to enable them to prescribe medicines, but that the scheme was being delayed by the Commonwealth's failure to subsidise medicines under the PBS.<sup>9</sup> South Australia allowed optometrists to prescribe eye drops in 2007.<sup>10</sup>

In a report to the Council of Australian Governments (COAG) on the health workforce in 2006, the Productivity Commission considered the issue of prescribing rights under the PBS:

Under Medicare, access to most subsidised specialist services is subject to a referral from a GP. For example, the Australasian College of Podiatric Surgeons (sub. 131, p. 7) referred to the lack of MBS rebates for the services of medical specialists in cases when a patient is referred by a podiatric surgeon. Similarly, pathology tests must generally be ordered by medical practitioners. Such referral restrictions aim to minimise the inefficient use of more specialised and high cost services, and to contain budgetary costs for government.

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4. *Health Insurance Act 1975*. This fulfilled an election promise by Gough Whitlam during the 1974 election campaign. The initial Medicare legislation, the *Health Insurance Act 1973*, had commenced on 8 August 1974.
  5. ACT Health Protection Service, *Prescribing of medicines by optometrists in the Australian Capital Territory. Discussion Paper*, Canberra, September 2003, pp. 5–7.
  6. [Optometrists Legislation Amendment Act 2005](#) (ACT).
  7. Hon. W. M. Edmond, 'Ministerial Statement: Optometrists', Queensland, *Debates*, 1 May 2003, p. 1562.  
[Health \(Drugs and Poisons\) Amendment Regulation \(No. 1\) 2005](#) (Qld), gazetted on 24 March 2005.
  8. *Poisons and Dangerous Drugs Amendment Act 2006* (NT).
  9. Sean Parnell, '[Optometrists find PBS delay is part of the new script](#)', *The Australian*, 5 May 2005, p. 4.
  10. *Optometry Practice Act 2007* (SA), s. 33.

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But referral restrictions have their own set of costs. In this respect, the Australian Physiotherapy Association argued that the inability of physiotherapists to directly refer patients for diagnostic imaging results in 9500 hours of unnecessary GP consultations each year, at an annual cost to the taxpayer of \$1 million, as well as additional time and monetary costs for patients (sub. 16, p. 18). Additionally, the Association contended that there would be further efficiency gains from granting physiotherapists the right to refer patients for MBS-supported consultations with specialists such as orthopaedic surgeons and obstetricians and gynaecologists.

Restrictions on who can prescribe drugs subsidised under the PBS similarly have some adverse consequences for the efficient deployment of the health workforce. For example, the Victorian Government referred to data collected by the Optometrists Association Victoria, suggesting that:

... approximately one out of eight patients who required a script were referred to a medical practitioner in order to be eligible for PBS subsidies, and that any increased costs associated with making PBS available to suitably qualified optometrists would be offset by savings to Medicare. (sub. 155, p. 33)

The Victorian Government went on to cite work by Halcomb et al. (2005), which suggests that the potential value of making MBS benefits available to a wider range of non-medical providers would be compromised by the current restrictions on PBS prescribing rights.<sup>11</sup>

The Productivity Commission recommended the establishment of a 'single, broadly-based and independent committee which would publicly advise the Minister for Health and Ageing' on this and other issues.<sup>12</sup> The Commonwealth Government, however, disagreed, preferring its existing advisory system.<sup>13</sup> Presumably this Bill is the outcome of further government consideration of specific measures that might be adopted as an alternative to the Productivity Commission's recommendation for systemic change.

The Australian Medical Association (AMA) has previously raised concerns regarding 'optometrists performing ophthalmological diagnoses and more interventions from a very restricted knowledge base.'<sup>14</sup> This concern was expressed in the context of other initiatives which were argued to sideline the role of GPs and specialists, with the AMA

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11. Productivity Commission, *Australia's Health Workforce*, Melbourne, 2005, p. 169.

12. *ibid.*, p. xxvi.

13. Council of Australian Governments, '[Attachment A: COAG Response to the Productivity Commission Report on Australia's Health Workforce](#)', 14 July 2006, linked from <http://www.coag.gov.au/meetings/140706/index.htm#attach>, accessed on 3 September 2007.

14. Dr M. Haikerwal, Federal AMA President, '[No substitute for a GP](#)', *Medical Observer Weekly*, 9 September 2005, p. 16.

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President commenting that ‘unsupervised role substitution’ does not satisfy the standard of equal access to high-quality medical services, regardless of geography or means.<sup>15</sup>

The framework through which optometrists will be able to prescribe PBS medicines is given some supervision through the regulatory structures introduced in the Bill.

In May 2006 the Royal Australian and New Zealand College of Ophthalmologists published a position statement proposing ‘a set of nationally consistent standards and principles’ to govern prescribing by optometrists.<sup>16</sup>

The Government announced the new measures in relation to optometrists at the time of the 2007 Budget.<sup>17</sup>

### Restrictions on pharmacists

Currently, section 90 of the Act provides for the Secretary of the Department of Health and Ageing to approve a pharmacist to supply pharmaceutical benefits ‘at’ or ‘from’ particular premises. Pharmaceutical benefits are medicines for which benefits will be paid by the Commonwealth (that is, medicines listed on the PBS schedule).

The Secretary can generally only approve a pharmacist if the Australian Community Pharmacy Authority (ACPA) has recommended that approval, and the pharmacist is permitted under the relevant state or territory law to carry on business as a pharmacist.<sup>18</sup>

The ACPA is required to consider all applications against location-based criteria which must be satisfied in order for a pharmacist to obtain approval to supply PBS medicines from particular premises. These criteria are set out in what are known as the pharmacy location rules. They include such things as the minimum distance between pharmacies and whether there is a community need for pharmaceutical services in a particular location.<sup>19</sup> The pharmacy location rules also prevent pharmacies which are located within, adjacent

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15. *ibid.*

16. Royal Australian and New Zealand College of Ophthalmologists, ‘Optometrists Therapeutic Prescribing’, <http://www.ranzco.edu/aboutus/ranzco-policies-and-procedures/position-statements/THERAP.PRESCRIBING.pdf>, May 2006, accessed on 4 September 2007.

17. The Hon. Tony Abbott, MP, Minister for Health and Ageing, *Better access to pharmaceutical products and services*, media release, Canberra, 8 May 2007. See also *Budget Paper, No. 2, 2007–08*, p. 248.

18. Australian Community Pharmacy Authority, *Applications Handbook*, Dept. of Health and Ageing, Canberra, March 2007, p. 2.

19. The Pharmacy Location Rules are contained in the [National Health \(Australian Community Pharmacy Authority Rules\) Determination 2006](#), as amended.

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to, or connected to, a supermarket, and to which members of the public have direct access from within the premises of the supermarket, from being approved to supply pharmaceutical benefits.

The purpose of the location rules is twofold: first, to provide widespread community access to pharmaceutical services, and second, to ensure the continued viability of existing pharmacies. The location rules have been somewhat controversial since their introduction in 1991, with some commentators and interest groups suggesting that they are a source of insufficient competition within the pharmacy sector.<sup>20</sup> Furthermore, in recent years the Woolworths retail chain has sought changes to the location rules in order to gain government permission for the establishment of in-store pharmacies.<sup>21</sup>

Once approved, pharmacists must also comply with a range of other conditions in order to continue to be able to supply pharmaceutical benefits: for example, a pharmacist can only supply benefits from the pharmacy that he/she is operating, and may not supply to anyone any pharmaceutical benefit that attracts a Commonwealth contribution for free, or for a price that is less than the relevant patient contribution.<sup>22</sup>

According to the Explanatory Memorandum, the rationale for the amendments in Schedule 2 of the Bill is to ‘clarify the intention of [the] Act’ in relation to the supply of pharmaceutical benefits ‘at’ or ‘from’ approved premises.<sup>23</sup> The Explanatory Memorandum suggests that the intention of the amendments is that, ‘at a minimum, members of the public will have access to pharmaceutical benefits ‘at’ the approved premises at reasonable times’.<sup>24</sup> This suggests that the intention of the Act was that

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20. See, for example, P. Kerin, ‘High price of anti-competition’, *Business Review Weekly*, 30 June 2005, p. 34; N. Ballenden, ‘The pharmacy: why it can’t stay a closed shop’, *Consuming Interest*, Winter 2005, pp. 18–20; M. Metherell, ‘Pharmacy profits hit a nerve’, *Sydney Morning Herald*, 16 May 2005, p. 1; B. Glasson, ‘Getting tough on turf’, *Australian Doctor*, 18 February, 2005, p. 21; A. Fels and F. Brenchley, ‘Dispense some competition to the pharmacies’, *Sydney Morning Herald*, 8 April 2004, p. 17; J. Albrechtsen, ‘Strip these white coats of subsidies’, *The Australian*, 1 September 2004, p. 15.
21. See for example, S. Mitchell, ‘Woolies resists drug-free future’, *Australian Financial Review*, 16 February 2006, p. 24; C. Jimenez and K. Murphy, ‘Woolies in pharmacy trial furore’, *The Australian*, 10 May 2005, p. 24; M. Polimeni, ‘Woolies in fresh pharmacy assault’, *Canberra Times*, 7 May 2005, p. 13; AAP, ‘Woolworths touts pharmacy trial’, *Australian Financial Review*, 9 May 2005, p. 17.
22. Department of Health and Ageing, ‘Supplying Medicines—What Pharmacists Need to Know’, PBS Explanatory notes for health professionals, <http://www.pbs.gov.au/html/healthpro/browseby/explanatory-notes?ref=section1-supplyingmedicines>, accessed on 4 September 2007.
23. *Explanatory Memorandum*, p. 2.
24. *ibid.*

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pharmacists be required to supply pharmaceutical benefits ‘at’ the particular premises for which they have been approved but may also choose to supply ‘from’ these premises (for example, to aged-care facilities and mail-order customers).

The Explanatory Memorandum and Second Reading Speech do not provide any explanation of why it has become necessary to clarify the intention of the Act through legislation. However, the Department of Health and Ageing has indicated (in correspondence with the Parliamentary Library) that the interpretation of the term ‘at or from’ expressed in a recent Federal Court decision<sup>25</sup> ‘*is inconsistent with the policy intent that an approved pharmacist must, at the very least, supply pharmaceutical benefits ‘at’ the particular premises for which he or she is approved*’.

The case in question was heard on appeal from the Administrative Appeals Tribunal. A Queensland pharmacist, Susann Holzberger, contested the cancellation of her approval to supply pharmaceutical benefits from a particular location for which she had been approved (known as the ‘West End Dispensary’). The cancellation was made by the Secretary of the Department of Health and Ageing on the grounds that Ms Holzberger was ‘not carrying on business as a pharmacist’ at this location (under subsection 98(3) of the Act).

The Secretary’s decision was made on the basis that Ms Holzberger was not dispensing PBS medicines to the public ‘at’ this location (a 3 x 3 m space that was formerly a storeroom). Rather, she was dispensing PBS medicines ‘from’ this location to another pharmacy (not approved to supply pharmaceutical benefits) located 375 metres away, from which the medicines were supplied to the public (known as the ‘West End Markets Pharmacy’). The Secretary (and later, the Administrative Appeals Tribunal) found that Ms Holzberger could not be considered to have been ‘carrying on the business of a pharmacist’ from the West End Dispensary on grounds including that ‘only the purely dispensing function’ is undertaken at that location (as opposed to the broader business of a pharmacy, including interacting with members of the public).

This finding was, however, overturned by the Federal Court on the grounds that section 90 of the Act ‘refers to supply ‘at or from’ the premises in question, indicating that the supply of pharmaceutical benefits need not necessarily occur ‘at’ the approved premises’.<sup>26</sup>

The Department’s concern with this decision relates to the potential it creates for pharmacists to avoid the requirements of the pharmacy location rules. That is, it implies that an approved pharmacy may supply pharmaceutical benefits to any number of unapproved premises which are not required to meet the pharmacy location rules (for example, the distance requirements). A further possible implication of concern to the Department is that approved pharmacies may operate as internet-only pharmacies that do

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25. [Holzberger v Secretary, Department of Health and Ageing](#) [2007] FCAFC 68.

26. *ibid.*, para. 20.

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not supply pharmaceutical benefits to members of the local community. This could have the effect of blocking approvals of pharmacies that intend to serve the local community but which cannot meet the distance requirements of the pharmacy location rules.

As such, the amendments in Schedule 2 appear to be intended to address what is effectively a ‘loophole’ created by the Federal Court decision in the Holzberger case (that is, the potential to avoid the requirements of the pharmacy location rules). While the Explanatory Memorandum does state that the purpose of the Schedule is to clarify the intention of the Act, it is notable that neither it nor the Second Reading Speech makes any specific mention of the Federal Court decision or the pharmacy location rules.

## Financial implications

The introduction of PBS prescribing by optometrists (**Schedule 1**) is expected to cost \$10.7 million over four years. Presumably this cost is derived from estimates of the number of prescriptions that have previously not been subsidised because people have been unwilling to pay the extra cost of going to a doctor for a prescription. The Explanatory Memorandum suggests that there will be a small offset of costs through a reduction in the number of doctor’s consultations paid by Medicare.

There is no cost to the government associated with the changes to legislation governing pharmacists (**Schedule 2**).<sup>27</sup>

## Main provisions

### Schedule 1–Optometrists

#### *Health Insurance Act 1973*

**Items 1–5** amend the *Health Insurance Act 1973* to include optometrists among those who are subject to the Professional Services Review Scheme, alongside the existing categories of doctors and dentists. Optometrists will be able to be suspended from supplying subsidised medicines for up to three years, in the same way as doctors and dentists can be suspended.

#### *National Health Act 1953*

**Item 8** inserts the same definition of *optometrist* as is used in the Health Insurance Act.

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27. *Explanatory Memorandum*, p. 3.

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**Item 9** inserts a definition of *PBS prescriber*. This will replace existing references just to doctors and dentists, and will encompass doctors, dentists and optometrists. Consequential amendments are made by items 10, 12, 14, 16, 18–36, 42–3, 45–52 and 64–7.

**Item 11** inserts **proposed sections 84AAB–AAC**, for the authorisation, suspension or revocation of optometrists as suppliers of pharmaceutical benefits. The Secretary of the Department of Health and Ageing has discretion to approve optometrists, and the Minister may (by disallowable legislative instrument) determine criteria for approval or conditions that can be attached to approval. The second reading speech noted that:

Optometrists will need to establish that they have the necessary professional registration and prescribing accreditation under state or territory requirements prior to approval to prescribe PBS medicines.<sup>28</sup>

It is unclear why these provisions are different from those that apply to dentists (s. 84A): applications from dentists must be approved by the Secretary, without discretion.

Approval of an optometrist may be suspended or revoked if he or she fails to meet the current criteria for approval or has breached conditions attached to approval. Before such a decision is made, an optometrist must be given 28 days' notice to allow him or her to make submissions.

**Proposed section 84AAD** provides for departmental review of decisions to suspend or revoke optometrists. These reviewed decisions may be appealed to the Administrative Appeals Tribunal (**item 44, proposed sub-section 105AB(2)**).

The provisions about the approval etc of optometrists commence on Royal Assent.

**Item 15** authorises approved optometrists to begin writing prescriptions for subsidised pharmaceuticals from 1 January 2008 (**proposed subsection 88(1C)**). The list of approved medicines is to be published in the *Gazette*.

## Schedule 2–Approved pharmacists

The amendments in Schedule 2 tighten the conditions applying to pharmacists who are approved to supply subsidised medicines. They will no longer be able to supply medicines solely by mail order, but will be obliged to be open to the public, and during reasonable business hours. (Pharmacists will still *also* be able to supply medicine to people who do not come physically to the pharmacy, including by mail (**item 8**).

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28. Sen. the Hon. Eric Abetz, '[Second reading speech: National Health Amendment \(Pharmaceutical Benefits\) Bill 2007](#)', Senate, *Debates*, 15 August 2007, p. 1.

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This effect is achieved mainly by removing several references to pharmacists being able to supply medicines ‘at or from’ premises, and replacing them with the term ‘at premises’ (**items 3–6, 9–15, 17, 19–20**).

The conditions of approval for pharmacists are amended by inserting a requirement for the business to be open during reasonable business hours, and a lack of business hours or a failure to supply are added to the criteria for the withdrawal of approval (**items 7, 16 and 18**).

## Concluding comments

The extension of PBS coverage to prescriptions being made by optometrists is a logical consequence of the legislative changes made in most of the states and territories in recent years, and will increase efficiency in the treatment of eye diseases. Although this was not a direct recommendation of the Productivity Commission’s report on [Australia’s Health Workforce](#), the Bill falls within the framework of wider prescribing rights that underlay that report’s recommendations.

The changes being made in Schedule 2 do not appear to have been the subject of public debate or commentary. They may be regarded as relatively uncontroversial in that they simply clarify the intent of the Act that pharmacists be required to supply pharmaceutical benefits ‘at’ the particular premises for which they have been approved but may also choose to supply ‘from’ these premises. It appears that the purpose of this is to address a ‘loophole’ created by the Federal Court decision in the Holzberger case that creates the potential for pharmacists to avoid the requirements of the pharmacy location rules. However, it is remarkable that neither the Explanatory Memorandum nor the Second Reading Speech makes any specific mention of the Federal Court decision or the pharmacy location rules.

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