



Health Legislation Amendment (Pharmacy Location Arrangements) Bill 2006

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Health Legislation Amendment (Pharmacy Location Arrangements) Bill 2006

Date introduced: 16 February 2006

House: House of Representatives

Portfolio: Health and Ageing

Commencement: Schedule 1, Part 1 commences on Royal Assent. Schedule 1, Part 2 and Schedule 2 commence 1 July 2006. Schedule 1, Part 3 commences immediately after the commencement of item 14 of Schedule 1 to the *National Health Amendment Act (No. 1) 2000*.

Purpose

The purpose of the Bill is to amend the *National Health Act 1953* (the Act) to make several changes to arrangements for approving pharmacists to provide medicines under the Pharmaceutical Benefits Scheme (PBS).

In summary, these amendments, which implement aspects of the Fourth Community Pharmacy Agreement between the Government and the Pharmacy Guild of Australia (the Guild) announced in November 2005, seek to:

- extend the operation of pharmacy location rules and their administration by the Australian Community Pharmacy Authority (ACPA) until 30 June 2010
- provide the Minister with discretionary power to approve a pharmacist not approved by the Secretary of the Department of Health and Ageing (DoHA) to supply PBS medicines
- make several changes to the pharmacy approval process designed to simplify arrangements for approving changes to pharmacies with existing approvals, and
- make several minor/technical amendments related to ACPA.

Background

Pharmacy location rules

Current arrangements require that applications by pharmacists to supply medicines subsidised through the PBS from either new or relocated premises must be referred to ACPA. The Secretary of DoHA, may only grant permission to supply PBS medicines following approval of an application by ACPA.

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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 and include such things as the minimum distance between pharmacies and whether there is a community need for pharmaceutical services in a particular location.¹ The pharmacy location rules also prevent pharmacies which are located within, adjacent 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, with some commentators and interest groups suggesting that they are a source of insufficient competition within the pharmacy sector.² Further, 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.³

The location rules and their administration by ACPA were reviewed as part of negotiations between the Government and the Pharmacy Guild of Australia for the Fourth Community Pharmacy Agreement. As can be seen below, the outcome of this review is that there will be no significant changes to the pharmacy location rules in the Fourth Agreement.

Fourth Community Pharmacy Agreement

On 8 November 2005 the Government announced that negotiations for the Fourth Agreement had been completed.⁴ The Fourth Agreement commenced on 1 December 2005 and will cease on 30 June 2010.

Negotiations between the Government and the Guild were protracted. The Fourth Agreement was finally announced some four months after the conclusion of the Third Agreement (30 June 2005).

On entering negotiations, the Government announced that it was seeking to achieve a reduction in the rate of growth of payments to the pharmacy sector ‘with the long-term aim of limiting pharmacy sector revenue to 0.4 per cent of GDP in 2040’ as part of its overall efforts to contain the cost of the PBS.⁵ The precise details of payments to pharmacists for dispensing PBS medicines (including whether the Guild would accept the Government’s proposed reduction of payments to pharmacists of up to \$460 million), were reportedly a source of some dispute in the negotiations.⁶ There is also some suggestion of dispute over the location rules during the negotiations—according to one media report, the Guild eventually accepted a reduction in fees order to avert the risk of a Government decision to change the location rules.⁷

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Details of the Fourth Community Pharmacy Agreement can be found in the Government's fact sheet at <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pharmacy-4cpafact>.⁸ In summary, the Government announced that the Fourth Agreement would include the following:

- \$11.1 billion in payments to pharmacists (amounting to \$350 million in savings against the forward estimates for the life of the agreement), including a reduction in the allowable mark-up for wholesaler costs, an increase in the pharmacists dispensing fee and the establishment of a Community Service Obligation (CSO) pool for direct payments to wholesalers who supply the full range of PBS medicines,
- new, more flexible location rules that, for example, allow pharmacies to co-locate with after-hours medical centres, relocate into certain types of shopping centres, single pharmacy towns and urban areas with high population growth, and
- retention of restrictions on pharmacies operating within supermarkets.

Commentary on agreement

Negotiations over community pharmacy agreements and the wider public debate over such agreements are complex and controversial for a variety of reasons. These include:

- the need of the Guild to advocate for the interests of its members
- perceptions in the pharmacy sector and the general public about threats to the continued viability of the community pharmacy sector—particularly in the light of the efforts of Woolworths to dispense pharmaceuticals (including accompanying concerns about 'small-scale', 'local' pharmacies being overcome by 'big', 'impersonal' retail chains)
- the Government's need to contain the overall cost of the PBS in the interests of sustainability, and
- concerns from a consumer point of view about the lack of genuine competition in the pharmacy sector.

On announcing the Fourth Agreement, the Minister for Health and Ageing, Mr Tony Abbott and Pharmacy Guild National President, Mr John Bronger, both noted that the agreement involved difficult compromises but was important for the sustainability of community pharmacies.⁹ Mr Abbott also emphasised the importance of agreed savings through changes to payments to wholesalers and pharmacists and the benefits to consumers of greater flexibility in the location.¹⁰

Nevertheless, Mr Bronger expressed some concern that the agreed system of payments, when combined with the expected continued reduction in demand for PBS medicines, would lead to a significant reduction in pharmacy income.¹¹ Since early 2005, there has been a slowing in expected demand for PBS medicines.¹² This reduction in demand has caused the Government to reduce its forecast figure for expenditure on the PBS for 2005-

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06 by \$283 million, meaning that the Government's expectations for growth in expenditure on the PBS for 2005-06 have been reduced from 7.3 per cent to below 2.5 per cent.¹³

Possibly as a result of reduced demand for PBS prescriptions, the Government has since revised expected savings from the agreement from \$350 million to \$306.8 million.¹⁴ There is also some dispute over the extent to which any such savings will directly impact upon community pharmacists. As one media report has noted, under the Fourth Agreement, pharmacists will be protected from a reduction in prescription volumes through access to higher dispensing fees—that is, if the number of prescriptions filled by community pharmacists drops to less than 95 per cent of that forecasted in the agreement (186.2 million in 2006), they will receive a higher dispensing fee.¹⁵

Basis of policy commitment

The Government describes the approach to regulation of the community pharmacy sector contained in the Fourth Agreement as 'targeted easing of the existing rules'.¹⁶ According to the Government, under this approach:

... current restrictions on the location of new pharmacies and the relocation of approved pharmacies would be relaxed, and exemptions widened, with the aim of improving flexibility and increasing competition within the existing community pharmacy sector.¹⁷

Alternative approaches discussed as part of the Fourth Agreement negotiations included

- retaining the existing arrangements, and
- adopting a new model based around remuneration-based incentives, where the approval and location of pharmacies could be influenced through differential dispensing fees.¹⁸

According to the Government, the first of these options (status quo) was rejected on the grounds that, while it might provide greater certainty to pharmacists approved under current arrangements, there were numerous problems with these arrangements that needed to be addressed.¹⁹ The remuneration-based incentives model, while offering potential benefits in terms of increasing access to pharmaceutical services in under-serviced communities, was also ultimately rejected as likely to be complex (administratively) and controversial, and 'to result in dispute with the community pharmacy industry'.²⁰

As such, the Government decided to pursue the 'targeted easing' option as one 'more likely to achieve a balance that is acceptable to the Government, the pharmacy industry and consumers, than the other alternatives canvassed'.²¹

This Bill therefore seeks to give effect to some of the 'targeted easing of the existing rules' contained in the Fourth Community Pharmacy Agreement.

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Structure of the Bill

Schedule 1, Part 1 provides for ACPA and the rules it administers to continue until 30 June 2010 (that is, the end of the Fourth Agreement).²²

Schedule 1, Part 2 provides for the inclusion of a consumer representative on ACPA. This will increase membership of ACPA from five to six members. The additional member will be ‘someone who, in the Minister’s opinion, is an appropriate person to represent the interests of consumers’.²³ The Consumer representative will be subject to the same rules as the existing members of ACPA (other than the DoHA representative).

Schedule 1, Part 3 seeks to make two minor technical amendments to the Act, correcting a cross-reference and punctuation.²⁴

Schedule 2, Part 1 seeks to provide the Minister with discretionary power to approve a pharmacist not approved by the Secretary of DoHA to supply PBS medicines. According to the Government, this power is intended to address unforeseen consequences of the application of the pharmacy location rules:

In some instances, the pharmacy location rules may operate to prevent the approval of a pharmacist, and result in a community being left without reasonable access to the supply of pharmaceutical benefits by an approved pharmacist.²⁵

The Government further notes that the limits applying to the Minister in exercising this power will include:

- the discretionary power only applies to applications made after 1 July 2006
- the Minister must be satisfied that the Secretary’s decision will result in a community being left without reasonable access to the supply of pharmaceutical benefits and that the approval is in the public interest
- the discretionary power can only be exercised at the completion of the existing approval process
- the discretionary power can only be exercised by the Minister personally (though he or she may seek additional information from other parties).²⁶

Further, pharmacists will still be entitled to seek a review of the Secretary’s decision through the Administrative Appeals Tribunal or an application to the Federal Court under the *Administrative Decisions (Judicial Review) Act 1977* if they are unsuccessful in requesting that the Minister use their discretionary power and they have not already exhausted these avenues of appeal. Affected parties may also seek the review of any decision made by the Minister regarding use of the discretionary power through an application under the *Administrative Decisions (Judicial Review) Act 1977*.²⁷

This Part also:

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- sets out the processes under which an applicant may make a request of the Minister
- provides that the Secretary may approve more than one pharmacist to supply pharmaceutical benefits from a particular premises (in instances where a pharmacist has ceased trading at a particular (original) premises in preparation for relocating to new premises and another pharmacist has sought approval to supply PBS medicines from the original premises) and
- clarifies that the Minister has the power to determine conditions for approval for pharmacists that relates to the premises from which pharmaceutical benefits are supplied.²⁸

Schedule 2, Part 2 seeks to amend the Act to make it possible for the Secretary to approve a pharmacist's application to expand or contract their premises without prior recommendation by ACPA.²⁹

Commentary on the Bill

While, as noted above, issues related to the pharmacy location rules are particularly controversial, the specific measures contained in this Bill are either relatively procedural or aimed at addressing anomalies and rigidities in the current arrangements. As such, they have not attracted significant public commentary or analysis.

The Government's 'targeted easing' approach to pharmacy regulation has not pleased some who see the Fourth Agreement as affording the community pharmacy sector a level of protection from competition not available to other sectors of the economy and would prefer a more radical approach to reform of pharmacy regulation.³⁰ While not as strong in his criticism of the Fourth Agreement as some contributors to the public debate, Australian Medical Association (AMA) President, Dr Mukesh Haikerwal has stated that it 'should be the last Agreement unless it can be shown to clearly provide a strong public benefit—not just a benefit to pharmacists and the Pharmacy Guild'.³¹

Further, as noted above, while both the Government and the Guild appear to agree that the Fourth Agreement provides at least some additional security to the community pharmacy sector (despite some misgivings on the part of the Guild about potential loss of income as a result of decreased demand for pharmaceuticals), questions do remain about the extent to which the easing of the location rules will improve access to pharmaceutical services in under-serviced areas. According to Dr Haikerwal, 'it is unclear how the relaxation of the location rules will improve access, and [the AMA] ask[s] the Government and the Pharmacy Guild to make public their expectations of how the relaxed rules will increase the number of pharmacies'.³²

According to one media report, there is some doubt over whether the new location rules allowing pharmacies to be established in large medical centres and smaller shopping centres will actually lead to a significant increase in access to pharmaceutical services.³³ According to the report, under the new rules, pharmacies will only be given approval to set up in large medical centres and smaller shopping centres if there is no existing pharmacy

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within 500 metres.³⁴ The article quotes a consultant whose firm represents pharmacists seeking pharmacy approvals, Mr Steven Holzberger, as saying that ‘there would be very few shopping centres of the size contemplated by this rule that do not have a pharmacy within 500 metres’ and ‘I would be very surprised if there were any successful applications under the proposed medical centre rule’.³⁵ In response, a spokeswoman for Mr Abbott stated that the 500 metre rule represented a reduction from the previous rule of 1.5 kilometres and that ‘the new arrangements will allow for an increased level of competition between pharmacies, while aiming to limit clustering of pharmacies in areas which are already well serviced’.³⁶

Thus, while the relevant measures in this Bill certainly appear to move the pharmacy location rules in the direction of greater flexibility and responsiveness to consumers, it remains unclear whether this will have a direct impact on access to pharmaceutical services by patients in under-serviced areas.

Financial implications

The Bill is not expected to have a direct financial impact.

Main provisions

Schedule 1—Australian Community Pharmacy Authority (ACPA)

Items 1 and 2 provide for ACPA and the rules it administers to continue until the end of the Fourth Agreement (30 June 2010).

Items 3 and 4 provide for the inclusion of a consumer representative on ACPA and the rules applying to this representative.

Items 5 and 6 make minor technical amendments to the Act, correcting a cross-reference and punctuation.

Schedule 2—Approval of pharmacists

Items 1, 4, 5 and 6 provide the Minister with certain discretionary powers to approve a pharmacist not approved by the Secretary of the DoHA to supply PBS medicines. **Item 4** inserts **new sections 90A—90E** into the Act.

Existing subsection 90(5) of the Act provides that the Secretary, DoHA, will notify applicants of the decision in relation to their application to supply pharmaceutical benefits. **Item 2** adds a note to make clear that in certain circumstances the Minister has the power to approve a pharmacist not approved by the Secretary of DoHA to supply PBS medicines.

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Item 3 makes clear that the Secretary, DoHA, can approve more than one pharmacist in respect of particular premises for the purposes of supplying pharmaceutical benefits.

Item 7 inserts a **new section 105AE** which ensures that an applicant's rights of review of the Secretary's decision in relation to an application are not limited because of an application to the Minister to exercise the discretionary powers outlined in Items 1, 4, 5 and 6.

Items 8—13 provide the Secretary of DoHA with the power to approve a pharmacist's application to expand or contract their premises without prior recommendation by ACPA and inserts various conditions applying to the exercise of this power.

Concluding comments

The measures contained in this Bill are either essentially technical/procedural or aimed at addressing anomalies and rigidities in the current arrangements. As such, they are relatively uncontroversial.

Nevertheless, while they appear to satisfy to some extent the aim of the Government, the Pharmacy Guild and many in the community of providing greater security to the community pharmacy sector, it is unclear whether they will satisfy the Government's additional objective of increasing access to pharmaceutical services in under-serviced areas. Given the controversial nature of community pharmacy agreements (in particular, the claims by some commentators that such agreements are essentially anti-competitive and hence not in the interests of consumers), the level of community access to pharmacy services will undoubtedly be monitored closely by many observers of the sector during the life of the Fourth Agreement should this Bill be passed by the Parliament.

Endnotes

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1. A consolidated version of the Pharmacy Location Rules can be accessed from the Australian Community Pharmacy Authority website at: <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-pharmacy-acpa-consdeterm.htm> (accessed 22 February 2006).
 2. 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; B. Glasson, 'Getting tough on turf', *Australian Doctor*, 18 February, 2005; A. Fels and F. Brenchley, 'Dispense some competition to the pharmacies',

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- Sydney Morning Herald*, 8 April 2004; J. Albrechtsen, 'Strip these white coats of subsidies', *Australian*, 1 September 2004.
3. See for example, S. Mitchell, 'Woolworths resists drug-free future', *Australian Financial Review*, 16 February 2006, C. Jimenez and K. Murphy, 'Woolies in pharmacy trial furore', *Australian*, 10 May 2005; M. Polimeni, 'Woolies in fresh pharmacy assault', *Canberra Times*, 7 May 2005; AAP, 'Woolworths touts pharmacy trial', *Australian*, 9 May 2005.
 4. Hon. Tony Abbott, Minister for Health and Ageing, 'Fourth Community Pharmacy Agreement', *Media release*, 8 November 2005.
 5. Hon. Tony Abbott, Minister for Health and Ageing, 'Fourth Community Pharmacy Agreement', *Media release*, 18 April 2005.
 6. See for example, M. Metherell, 'Drug deal keeps pharmacy out of Woolies', *Sydney Morning Herald*, 8 November 2005; A. Stafford, 'Pharmacists have prescription for higher fees', *Australian Financial Review*, 11 November 2005.
 7. Metherell, 'Drug deal keeps pharmacy out of Woolies', op. cit.
 8. The text of the Fourth Agreement can be obtained from:
[http://www.health.gov.au/internet/wcms/publishing.nsf/Content/F7FBDB333D030BFFCA2570C00003A44/\\$File/4CPA.pdf](http://www.health.gov.au/internet/wcms/publishing.nsf/Content/F7FBDB333D030BFFCA2570C00003A44/$File/4CPA.pdf), accessed 22 February 2006.
 9. Hon. Tony Abbott, Minister for Health and Ageing, 'Press conference on the Fourth Community Pharmacy Agreement with John Bronger, National President, Pharmacy Guild of Australia, Parliament House, Canberra, Tuesday 8 November 2005', *Media release*, 8 November 2005, pp. 1-3.
 10. *ibid.*, p. 1.
 11. Abbott, 'Press conference on the Fourth Community Pharmacy Agreement with John Bronger, National President, Pharmacy Guild of Australia, Parliament House, Canberra, Tuesday 8 November 2005', op. cit.
 12. See, for example, A. Stafford 'Runaway PBS costs slowing', *Australian Financial Review*, 4 October 2005; A. Creswell, 'PBS clampdown saves \$300 million', *Australian*, 9 August 2005.
 13. *Mid-Year Economic And Fiscal Outlook 2005-06*, Australian Government, December 2005, p.23, at <http://www.budget.gov.au/2005-06/myefo/html/index.htm>, accessed 9 February 2006.
 14. *ibid.*, p. 160. See also A. Stafford, 'Pharmacists have prescription for higher fees', op. cit.
 15. A. Stafford, 'Pharmacists have prescription for higher fees', op. cit.
 16. Explanatory Memorandum, p. 7.
 17. *ibid.*
 18. *ibid.*, p. 6.
 19. *ibid.*, p. 7.
 20. *ibid.*, pp. 9-10.

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21. *ibid.*, p. 11.
22. *ibid.*, p. 1.
23. *ibid.*, p. 1.
24. *ibid.*, p. 1.
25. *ibid.*, p. 2.
26. *ibid.*, p. 2.
27. *ibid.*, pp. 2–3.
28. *ibid.*, pp. 2–3.
29. *ibid.*, p. 3.
30. See for example, ‘Latest broken promise from Minister Abbott’, *Courier Mail*, 10 November 2005; ‘Pharmacists’ deal a protectionist farce’, *Australian Financial Review*, 22 November 2005.
31. Dr Mukesh Haikerwal, President, Australian Medical Association, ‘Fourth Community Pharmacy Agreement must be closely monitored for public benefit’, *media release*, 8 November 2005.
32. *ibid.*
33. A. Stafford, ‘Radius rule a bitter pill for chemists’, *Australian Financial Review*, 11 November 2005.
34. *ibid.*
35. *ibid.*
36. *ibid.*

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