



National Health Amendment (Pharmaceutical and Other Benefits—Cost Recovery) Bill 2008

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Contents

Purpose.	2
Background.	2
Basis of policy commitment.	3
Position of significant interest groups/press commentary	4
Pros and cons	5
Comparison with government tendering process	5
Independence of the PBAC	5
Comparisons with TGA and other government programs.	6
Principles of cost recovery.	7
Timing of implementation and possible unintended consequences	8
Financial implications	9
Main provisions.	10
Schedule 1 – Cost Recovery.	10
Proposed new section 99YBA	10
Proposed new section 99YBB.	11
Concluding comments	11

National Health Amendment (Pharmaceutical and Other Benefits—Cost Recovery) Bill 2008

Date introduced: 29 May 2008

House: House of Representatives

Portfolio: Health and Ageing

Commencement: Sections 1 to 3 of the Bill commence on Royal Assent
Schedule 1 amendments commence on 1 July 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

The purpose of the National Health Amendment (Pharmaceutical and Other Benefits—Cost Recovery) Bill 2008 (the Bill) is to amend the *National Health Act 1953* (the Act) by introducing provisions that will authorise the Commonwealth Government to impose fees, and thereby recover costs associated with the services and activities related to listing medicines on the Pharmaceutical Benefits Scheme (PBS) or designating vaccines for the National Immunisation Program (NIP).¹

The fees, which would generally be paid by the pharmaceutical industry, will be prescribed in the regulations under the Act.

Background

The PBS ensures reliable, timely and affordable access to prescription pharmaceuticals to Australian citizens and permanent residents. It has been in operation for around 60 years and is considered a key feature of the Australian health care system. For a drug to be listed on the PBS it must have marketing approval from the Therapeutic Goods Administration (TGA) and receive a positive recommendation from the Pharmaceutical Benefits Advisory Committee (PBAC).

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1. Nicola Roxon, Minister for Health and Ageing, 'Second Reading Speech: National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008, House of Representatives, *Hansard*, 29 May 2008, p. 65.

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The PBAC is the Committee which advises the Minister for Health and Ageing as to which pharmaceuticals should be listed on the PBS and which vaccines are to be funded under the National Immunisation Program (NIP). When making a recommendation about a pharmaceutical, the PBAC takes into account the comparative efficacy and cost-effectiveness to products already listed on the PBS. Under the Act, the Minister cannot list a drug on the PBS (or fund a vaccine) unless that drug or vaccine has received a positive recommendation from the PBAC.

The NIP is a joint program of Commonwealth and State/Territory governments which provides fully funded vaccines for major preventable diseases. As with most health programs, the Commonwealth provides the funding and the service is delivered by the State/Territory governments. Vaccines listed on the NIP are considered by the PBAC.

This Bill enables the implementation of a 2008-09 Budget measure announced in the Health and Ageing portfolio. The introduction of cost recovery arrangements for all submissions lodged to the PBAC on or after 1 July 2008, is expected to generate additional revenue of \$7 million over four years, with a net cost of \$2.2 million.²

The proposal involves two payment points for fees - the first for receipt of submission and consideration by the PBAC and the second for pricing and listing activities following a positive PBAC recommendation.³ Any subsequent consideration by the PBAC, for example – resubmissions, will be subject to further fees. The fees will be prescribed by regulations. There is provision in the legislation for review of the fees by the Administrative Appeals Tribunal.

Basis of policy commitment

Cost recovery arrangements were first announced in the 2005–06 Budget, with a proposed implementation date of 1 July 2007. Implementation was deferred due to consultations with the pharmaceutical industry about the Pharmaceuticals Benefits Scheme Reform process during 2006.⁴ This measure was described in the 2008-09 budget papers as an election commitment, but it has not been possible to locate the introduction of cost recovery to Pharmaceutical Benefits Advisory Committee (PBAC) processes in the ALP election platform or other health policy documents.

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2. Australian Government, 'Part 1: Revenue Measures', *Budget Paper No. 2: Budget Measures 2008–09*, Commonwealth of Australia, Canberra, 2007, p. 9. But see also discussion under the 'Financial Implications' section of this Digest.
 3. Nicola Roxon, Minister for Health and Ageing, *op. cit.*, p. 66.
 4. Department of Health and Ageing, *Annual Report 2006-07*, Commonwealth of Australia, p. 53.

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Position of significant interest groups/press commentary

When the cost recovery arrangements were first announced in the 2005-06 Budget, there was widespread concern about the introduction of this measure undermining the independence of the PBAC and possibly resulting in manufacturers declining to list products on the PBS (especially for low volume products).⁵

Those concerns remain. The peak lobby group for pharmaceutical manufacturers in Australia, Medicines Australia, expressed surprise and disappointment at the announcement of the measure on Budget night.⁶ They argued that operation of the PBS was essentially a Commonwealth Government function and it was 'inappropriate' for cost recovery arrangements to be introduced.⁷

In the press, there were fears that this measure could undermine the independence of the PBAC and result in higher drug prices to consumers.⁸

It is noted that the possible impact on the generic medicines industry has not been widely considered in the public debate.

Prior to the Budget 2008-09 announcement, the chair of the PBAC, Professor Lloyd Sansom, noted that the PBAC did not have a view on the issue and suggested that cost recovery arrangements would not affect its recommendations. Professor Sansom commented that it would be 'business as usual'.⁹

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5. See, for example, B. Grabau, 'Cost-recovery drive could impact on sustainability on the PBS,' *Canberra Times*, 18 May 2005, http://parlinfoweb.aph.gov.au/piweb/TranslateWIPILink.aspx?Folder=pressclp&Criteria=CITATION_ID:E32G6%3B, accessed on 19 May 2008.
 6. Medicines Australia, *Medicines Australia surprised by PBAC measure*, media release, 13 May 2008, http://www.medicinesaustralia.com.au/pages/view_news.asp?id=81, accessed on 19 May 2008.
 7. *ibid.*
 8. S. Ryan, 'Drug committee left to rely on industry funding', *The Australian*, 15 May 2008, p. 9, http://parlinfoweb.aph.gov.au/piweb/TranslateWIPILink.aspx?Folder=pressclp&Criteria=CITATION_ID:C0GQ6%3B, accessed on 19 May 2008.
 9. P. Smith, 'Labor rethink on pharma funding PBAC', *Australian Doctor*, 15 Feb 2008, p.7: http://parlinfoweb.aph.gov.au/piweb/TranslateWIPILink.aspx?Folder=jnart&Criteria=CITATION_ID:9VNP6%3B, accessed on 28 May 2008.

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Pros and cons

One of the main arguments put forward in favour of cost recovery is that there is significant financial benefit to a pharmaceutical company for a product to be listed on the PBS and that it is not ‘unreasonable’ for the taxpayer incurred costs associated with listing to be recovered.¹⁰ Companies with products listed on the PBS receive considerable financial benefit.

Comparison with government tendering process

Some comparisons may be drawn between listing products on the PBS and Commonwealth Government procurement processes such as tendering. In both instances, the applicant receives a financial benefit from positive selection. Currently, the Commonwealth Government does not charge tenderers as part of the tender submission process. It could be argued that the costs associated with developing a tender submission is a substitute for a fee. Similarly, the pharmaceutical industry expends considerable effort when developing a PBAC submission, at a cost to the manufacturer. Under the cost recovery arrangements, the pharmaceutical industry will be required to fund the development of the submission and also pay a fee when the submission is considered by the PBAC.

Independence of the PBAC

In the second reading speech, the Minister has noted that the proposed implementation model addressed the concerns about independence of the PBAC. The Commonwealth Government will continue to directly fund the operations of the PBAC and the revenue generated will become part of consolidated revenue. In this way, the model is expected to guarantee the independence of the PBAC.

The independence of the PBAC has always been considered paramount in the operation of the PBS. It operates at arms length from the Commonwealth Government and the Minister. Its importance is enshrined in the legislation and the Minister for Health cannot list a drug on the PBS or fund a vaccine on the NIP without a positive recommendation from the PBAC.

The Commonwealth Government is confident that the shift towards cost recovery arrangements will not undermine the independence of the PBAC.¹¹ Given the comments

10. Nicola Roxon, Minister for Health and Ageing, op. cit., p. 66.

11. See Nicola Roxon, Minister for Health and Ageing, Second reading speech and Justine Elliot, Minister for Ageing, Parliamentary Debates, House of Representatives, 5 June 2008, *Hansard*, p. 22.

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made by Professor Lloyd Sansom prior to the announcement, it would appear that the changes will not have any material impact on the operation of the PBAC. However, the perception of a conflict of interest (real or perceived) lingers for some¹².

Comparisons with TGA and other government programs

Comparisons have been made between the TGA and the work of the PBAC. Specifically, cost recovery has been implemented successfully in the TGA and the TGA has maintained its independence.¹³ Examples of other agencies such as the Civil Aviation Safety Authority and the Australian Prudential Regulatory Authority where cost recovery arrangements had been successfully implemented have also been presented.

The Department of Health and Ageing (DoHA) has argued that as the TGA operates under cost recovery arrangements, it is a 'logical extension' for the PBAC to operate under the same arrangements.¹⁴ However, the TGA and PBAC have vastly different roles: the TGA determines whether a drug (or medical device) can be marketed in Australia whereas the PBAC recommends to the Minister which drug should receive public subsidy on the PBS and which vaccines should be publicly funded under the NIP.

In the context of public reimbursement or subsidisation for medical products (pharmaceuticals or vaccines), cost recovery arrangements have rarely been used. There is only one other publicly funded program that operates on principles of cost recovery - the evaluation of prostheses for listing on the Medicare Benefits Schedule exist. It was introduced to reduce public expenditure on prostheses which had been increasing significantly.¹⁵ In contrast, cost recovery for pharmaceuticals and vaccines is being introduced to 'offset the additional costs' associated with evaluating and listing new products on the PBS.¹⁶ Given these vastly different objectives, comparisons between the two are difficult, except to note that pharmaceuticals are widely used in the community

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12. Please refer to media reports such as S. Ryan, 'Drug committee left to rely on industry funding', *The Australian*, 15 May 2008, p. 9. See also Dr Mal Washer, Parliamentary Debates, House of Representatives, 5 June 2008, *Hansard*, p. 20.
 13. Nicola Roxon, Minister for Health and Ageing, op. cit., p. 65.
 14. Cost recovery for evaluation and listing on the Pharmaceutical Benefits Scheme (PBS) and National Immunisation Program (NIP) – Frequently Asked Questions, http://www.pbs.gov.au/html/healthpro/factsheet/view?date=20080501&type=XML&name=Health_Professional_Cost_Recovery_FAQ&folder=cost_recovery&area=professional, accessed on 13 May 2008.
 15. Department of Health and Ageing, *Prostheses list—guide to listing and setting benefits for prostheses. Part 1: understanding the prostheses arrangements*, November 2007, <http://www.aph.gov.au/library/pubs/cib/2001-02/02cib12.htm>, accessed on 15 May 2008.
 16. Australian Government, op. cit., p. 9 (*Budget Paper 2*).

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and the PBS (including the listing process) is an integral part of the delivery of timely and affordable access to medicines.

Principles of cost recovery

According to the Productivity Commission, cost recovery arrangements should only be introduced to ‘improve economic efficiency’ and ‘cost recovery should not be implemented where ... it would be inconsistent with policy objectives’.¹⁷ This view is also echoed in the Commonwealth Government’s Cost Recovery Guidelines.¹⁸ While subjecting the assessment of medicines to cost recovery may well increase economic efficiencies, one of the unanswered questions is whether the introduction of cost recovery arrangements undermines Commonwealth Government health policy objectives in relation to timely and affordable access to essential medicines. As the primary focus of the PBS is ‘timely and affordable access at a cost the community can afford’, charging companies for the products to be listed on the PBS may lead to delays in listings and higher drug prices for the Commonwealth Government. If this were to be the result it would not be consistent with the Commonwealth Government’s health policy objectives.

However, the Minister has emphasised the Productivity Commission’s support for the principles of cost recovery. It was suggested that their introduction may potentially increase compliance with PBAC Guidelines, reduce the time and costs associated with resubmissions and improve the overall quality of PBAC submissions.¹⁹ Development of a submission to the PBAC is a complex and time consuming exercise and any delays with PBAC recommendations have financial implications for companies. It is possible that this already serves as sufficient motivation for the pharmaceutical industry. In addition, DoHA and the chair of the PBAC actively work with the pharmaceutical industry to promote understanding of the PBAC guidelines and requirements for submissions with regular meetings and transparent processes.²⁰ Therefore, it remains to be seen whether the introduction of a fee will improve the overall quality of submissions (and re-submissions) and reduce the time associated with re-submissions.

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17. Productivity Commission, *Cost recovery by Government agencies*, Report no.15, AusInfo, Canberra, 2001, p. 175.
 18. Commonwealth of Australia, *Australian Government Cost Recovery Guidelines*, Canberra, 2005, p. 5, http://www.finance.gov.au/finframework/docs/Cost_Recovery_Guidelines.pdf, accessed on 14 May 2008.
 19. Explanatory Memorandum, op. cit., p. 3.
 20. Please refer to PBAC’s web page on the DoHA website about meeting availability: <http://www.healthconnect.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-listing-dates.htm>, accessed on 30 May 2008.

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Timing of implementation and possible unintended consequences

The proposed implementation date of 1 July 2008 puts considerable pressure on DoHA and the pharmaceutical industry. Although DoHA has released a Frequently Asked Questions document explaining the changes²¹, information sessions about the proposed implementation have been set for 10 and 12 June 2008, some three weeks before implementation is due to commence and a month before the due date for major submissions for consideration at the next PBAC meeting.²² These submissions will be subject to cost recovery processes.

Indicative fees and charges were released by DoHA the day before the legislation was due to be debated in Parliament (4 June 2008). At the time of publication, the fees and charges had not been tabled in Parliament. Indicative fees were as follows:²³

- Major submission \$119 500
- Minor submission \$12 500
- Secretariat listing \$1 000
- Generic products \$500
- Pricing arrangements²⁴ \$25 000

Commentary on the indicative fee structure has focussed on the total cost to the pharmaceutical industry to bring a product to market. For new products (such as new cancer drugs) the cost will be around \$315 000, provided there are no complications.²⁵ This is perhaps a conservative estimate. A review of the PBAC meeting outcomes suggests that it is rare for a major submission to receive a positive recommendation on its

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21. Refer to 'Information update regarding PBS cost recovery' on the PBS website (www.pbs.gov.au)
http://www.pbs.gov.au/html/healthpro/news/article?id=NEWS-2008-05-20-Information_Update_regarding_PBS_Cost_Recovery.xml, accessed on 29 May 2008.
 22. Please refer to PBAC Cycle Timeframe for 2007-08,
<http://www.healthconnect.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-listing-dates.htm>, accessed on 30 May 2008.
 23. N. Lush, 'Govt announces massive PBS fees', published online 4 June 2008 by Pharma in Focus, <http://www.pharmainfocus.com.au/news.asp?newsid=2326>, accessed on 4 June 2008.
 24. For 'Tier 2 and Tier 3' medicines. These classifications have been developed by DoHA. Tier 2 medicines require PBAC consideration and Tier 3 medicines require PBAC and Cabinet consideration.
 25. N. Lush, op cit.

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first consideration by the PBAC.²⁶ As yet, no advice has been provided about how ‘deferrals’ or ‘resubmissions’ will be costed. In addition, pricing negotiations can take considerable time and it is not clear if each round of pricing negotiations will be subject to a \$25,000 fee.

An unintended consequence of this policy may be that it will now become more difficult for non-industry bodies (for example, clinicians or patient groups) to apply for products to be listed on the PBS. There are no restrictions on who can make a submission to the PBAC. In order to be considered by the PBAC, submissions must fulfil the technical requirements. Given the total estimated cost for a major submission, it may be difficult for clinicians or patient groups to raise the necessary funds to not only prepare the submission, but also to have it considered by the PBAC. The proposed cost recovery arrangements may therefore well act as a barrier to their applying. It should be noted that there is provision in the Bill for exemption and waiver of fees. Although the Bill does not define the circumstances in which this can be applied, the second reading speech notes that an exemption could be applied ‘when it is in the public interest’.²⁷

Another possible unintended consequence of the Bill is higher costs of pharmaceuticals. As it will be necessary for the industry to recoup these additional costs, it may lead to higher prices for pharmaceuticals and a subsequent increase in cost to the Commonwealth Government. This possibility was acknowledged by senior DoHA officials during a Senate Estimates hearing in 2005.²⁸

Financial implications

The Explanatory Memorandum states that once fully operational, annual revenue from fees is expected to total about \$9.4 million in 2008-09 rising to around \$14 million in 2009-10.²⁹ This is in contrast to what was announced in Budget 2008-09 — that this measure was expected to generate additional revenue of \$7 million over four years, with a net cost of \$2.2 million.³⁰

26. Refer to the ‘PBAC Outcomes and Public Summary Documents’ on the DoHA website:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/pbac-outcomes-and-public-summary-documents>

27. See Nicola Roxon, Minister for Health and Ageing, Second reading speech.

28. Community Affairs Legislation Committee, *Budget Estimates*, 1 June 2005, CA125.

29. Explanatory Memorandum, op. cit., p. 1. See also Nicola Roxon, Minister for Health and Ageing, op. cit., p. 67.

30. Australian Government, op. cit., p. 9 (*Budget Paper 2*).

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Despite the discrepancy in figures, it is important to note that both figures are estimates only and the proposed revenue may not be realised. Furthermore, it is questionable that in the context of a \$7 billion dollar program (with a steady growth rate) that a predicted saving of between \$1.75 - \$9 million per year is going to have any material impact on the cost of the operation of the PBS. From a monetary perspective, it appears that the introduction of cost recovery for the public reimbursement of pharmaceuticals has more symbolic value. For example, the TGA recovers the full cost of all activities undertaken that are within the scope of the *Therapeutic Goods Act 1989*.³¹

As previously noted, concern has been expressed that the introduction of cost recovery arrangements may lead to higher prices for pharmaceuticals and a subsequent increase in cost to the Commonwealth Government. It has been predicted that the cost of bringing a pharmaceutical to market may double with the introduction of cost recovery fees.³²

Main provisions

Schedule 1 – Cost Recovery

Item 1 of the Bill proposes to insert a **new Division 4C**, which contains three new sections relating to cost recovery, into the Act. Particular attention will be paid to **proposed sections 99YBA and 99YBB**.

Proposed new section 99YBA

Proposed new subsection 99YBA(1) would enable regulations to be made concerning services provided by the Commonwealth Government in relation to its exercise of the following powers under the Act:

- the provision of vaccines under section 9B, and
- the PBS regime under Part VII.³³

31. Therapeutic Goods Administration, 'Cost recovery impact statement – annual review of fees and charges 2008-09 – Non-prescription (registered) medicines, May 2008, <http://www.tga.gov.au/fees/cris-npfees0809.htm>, accessed on 2 June 2008.

32. N. Lush, op cit.

33. For an explanation of what are the Minister's powers under section 9B and Part VII of the Act, see Explanatory Memorandum, National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Bill 2008, p. 3. For an explanation of relevant Commonwealth Government services, see *ibid*.

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Proposed new subsection 99YBA(2) provides that regulations may be made prescribing certain matters relating to services provided by the Commonwealth Government under section 9B and Part VII of the Act. Those matters include:

- applying for such services
- prescribing fees for such services
- when prescribed fees are payable, including extensions of time
- the manner of payment of prescribed fees
- penalties for late payment of prescribed fees
- exemptions from payment of prescribed fees
- waiver, remission or refund of prescribed fees, and
- review of decisions made under these regulations.

Proposed subsection 99YBA(3) provides that the prescribed fee must not amount to taxation.

Proposed subsection 99YBA(5) provides that a prescribed fee is a debt which is recoverable by the Commonwealth Government.

Proposed new section 99YBB

Proposed new subsection 99YBB(1) would give the Minister a discretion to refuse to exercise certain powers if the prescribed fee is not paid. Simply put, any consideration of the application may cease until the appropriate fee is paid. According to the second reading speech, a ‘tools down’ approach is envisaged until the fee is paid.³⁴

Under **proposed subsection 99YBB(2)**, such a refusal would not constitute a legislative instrument and consequently, would not be disallowable.³⁵

Concluding comments

This Bill gives the Minister for Health and Ageing the power to introduce cost recovery arrangements for the consideration of products to be listed on the PBS or funded under the NIP. It does not, however, provide much detail on proposed implementation of the

34. Nicola Roxon, Minister for Health and Ageing, op. cit., p. 67.

35. As to disallowance of legislative instruments, see *Legislative Instruments Act 2003* sections 42, 44.

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arrangements and, at the time of the parliamentary debate in the House of Representatives, only indicative fees and charges had been released by DoHA.

It remains to be seen whether the implementation of this measure will generate the predicted revenue for the Commonwealth Government and improve the overall quality of PBAC submissions.

What also remains to be seen is the impact on pricing of pharmaceuticals and whether this acts as a deterrent to the pharmaceutical industry (originator and generic) to have products listed on the PBS.

Discussion about the broader issues such as what constitutes Commonwealth Government business, has been largely absent from this debate. Arguably, the administration of the PBS could be considered ‘core’ government business and it consequently could be argued that the associated costs should be met by the Commonwealth Government.

Should the proposed scheme go ahead, Australia is likely to be one of the first countries in the world to introduce cost recovery arrangements for the (public) reimbursement of pharmaceuticals and funding for vaccines.³⁶ The Commonwealth Government’s stated benefits for introduction of these arrangements have yet to be realised and the predicted revenue is not significant. This shift to cost recovery sets a precedent in Australian health policy and the delivery of health care. Given its significance there has been very little examination or debate on the potential implications for health policy more broadly.

36. Cost recovery arrangements for the regulation of pharmaceuticals is a common international practice (for example, the US Food and Drug Administration and the European Medicines Agency all operate under cost recovery arrangements).

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