



National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007

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National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007

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Purpose

This Bill amends the *National Health Act 1953* (the Act) to introduce new arrangements for the determining the price the Government pays for medicines under the Pharmaceutical Benefits Scheme (PBS). These changes were [announced](#) as part of the PBS reform package in November 2006.

Measures introduced under the Bill include:

- the division of the Schedule of Pharmaceutical Benefits (the Schedule) into two 'formularies', one for single drugs (F1) and the other for drugs that have multiple brands or are interchangeable with drugs that have multiple brands (F2) (the latter formulary split into low competition (F2A) and high competition (F2T) sections until 1 January 2011)
- pricing rules for drugs in each formulary
- requirements that pharmaceutical companies disclose market price data to the Department of Health and Ageing to ensure that the price the Government pays for F2 drugs reflects the actual price paid by pharmacies, and
- requirements that suppliers of new generic or discounted medicines guarantee supply of these medicines for a specified period.

The Bill also includes provisions related to exceptions to the above changes and a range of minor, technical and consequential amendments.

Broadly, the purpose of the Bill is to establish pricing structures that will enable the Government to achieve greater savings in the price it pays for medicines into the future.

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Background

The PBS—an overview

The PBS provides universal, subsidised access to medicines to the Australian community. Along with Medicare and the public hospitals system, it forms a central component of Australia's health system. The PBS has been in operation for almost 60 years with some benefits first being made available in June 1948 and has evolved from supplying a limited number of 'life saving and disease preventing drugs' free of charge to the community, into a broader subsidised scheme.¹

Currently, the PBS subsidises access to more than 600 medicines, available in 1,800 forms and marketed as 2,600 differently branded items.² The PBS covered around 168 million prescriptions in the year to June 2006 (about eight prescriptions per person in Australia).³

The PBS covers all Australian residents when they fill a prescription for a medicine listed on the Schedule. General patients pay up to \$30.70 for PBS medicines, while those with concession cards (available to many people on low incomes) pay up to \$4.90. These payments are called patient contributions or copayments and are revised both annually in line with the Consumer Price Index (CPI) and on other occasions when the Government seeks to further increase the share of the cost of the PBS borne by individual patients (for example, the 30 per cent increase in copayments on 1 January 2005).

Government expenditure on the PBS for the year ending 30 June 2006 totalled \$6.163 billion, compared with \$6.001 billion for the previous year (an increase of around 2.7 per cent).⁴ This amounts to around 83 per cent of the total cost of PBS prescriptions. The remainder of PBS expenditure is made up of patient contributions of \$1.123 billion, up from \$1.040 billion in the previous twelve-month period.⁵ The 2007-08 budget papers suggest PBS expenditure will increase to \$6.433 billion in 2006-07 and \$7.279 in 2007-08.⁶

Sustainability of the PBS

The cost and future sustainability of the PBS have been a particular source of concern for the Government in recent years. This reflects the fact that Government PBS expenditure has been increasing at a very high rate for much of the last decade or so. For example, between 1994-95 and 2004-05, Government expenditure on the PBS increased by an average of 10.8 per cent per year. It also reflects longer term projections about the cost of the PBS raised, for example, in the Department of Treasury's 2002-03 [Intergenerational Report](#) and Productivity Commission's 2005 report, [Economic Impacts of an Ageing Australia](#).

There are a number of matters worth considering in relation to these figures. First, the most consistent trend in relation to PBS growth rates in recent years has been fluctuation, rather than a uniform trend towards decline, acceleration or stabilisation. This can be seen

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from the table illustrating past and projected expenditure below. This suggests that some caution should be used prior to drawing conclusions about future PBS growth based on previous averages. This is not to suggest that there will not be high rates of growth in the PBS into the future. The point is that it is difficult to predict precisely what the rates of growth will be. This is further underlined by the fact that the Treasury's [2007 Intergenerational Report](#) revised its initial projections for PBS expenditure from 3.4 per cent of GDP by 2044-45 to 2.5 per cent of GDP for the same period.⁷

Table 1: Australian Government expenditure on the PBS, 1994-95 to 2004-05

Year	Amount (\$millions)	Growth (%)
1994-95	2,128	
1995-96	2,545	19.6
1996-97	2,754	8.2
1997-98	2,814	2.2
1998-99	3,105	10.3
1999-00	3,537	13.9
2000-01	4,324	22.2
2001-02	4,683	8.3
2002-03	5,171	10.4
2003-04	5,660	9.5
2004-05	5,917	4.5

Source: Australian Institute of Health and Welfare, [Health Expenditure Australia 2004-05](#), p. 66 (Table 36)

Government policies

The issue of sustainability has been a consistent theme in recent Government policy-making on the PBS by both the current Coalition Government and previous Labor Governments. The Government has, over the previous decade or so, introduced a range of initiatives aimed at containing the cost of medicines under the PBS and ensuring the Scheme's future sustainability. These include increased patient copayments, efforts to increase price competition through the development of a generic medicines industry in Australia, programs aimed at changing prescribing behaviour, improved monitoring of

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entitlements to pharmaceutical benefits, and deletion of particular items from the Schedule.

The 2004–05 budget contained a particularly strong emphasis on the sustainability of the PBS and included a number of measures aimed both at achieving more or less immediate savings (worth approximately \$1.3 billion over the next four years) and developing a more sustainable framework for future expenditure. These included:

- changes to PBS safety net entitlements
- moving towards cost recovery funding for the administration of the [Pharmaceutical Benefits Advisory Committee](#) (PBAC) and the PBS listing process from 2007–08, and
- introduction of an automatic reduction of at least 12.5 per cent in the price paid by the Government for any PBS medicine following the listing of a generic version of that medicine. Under PBS ‘reference pricing’ arrangements, this reduced price automatically becomes the benchmark for the formerly patent-protected drug and any other drugs in the same pricing category.

The latter measure was widely criticised throughout the medicines sector as having been introduced without adequate consultation.⁸ Further, some also argued that a mandatory, blanket reduction of the type proposed by the Government would place increased cost pressures on the medicines industry, which may lead to some companies choosing to either withdraw or not apply for listing of particular medicines on the PBS, or for increased costs to be passed on to consumers in some way.⁹

Proposals for change to the PBS

The Government had reportedly been considering four further options for reforming the PBS in early 2006. According to media reports, these were:

- a system in which suppliers must compete to provide the subsidised medicine in a particular therapeutic group (similar to a system currently operating in New Zealand),
- a system in which the Government pays less for a generic drug every time the sales for the drug increase by a certain percentage,
- two alternative systems in which suppliers must compete to provide the lowest cost generic or copy-cat medicine once the patent of an originator medicine has expired:
 - under the first model, the prices of all other drugs in the same therapeutic group would be reduced to match the price of the winning tenderer’s drug. Only the winning tenderer would be allowed to offer patient discounts, making their drug 50 per cent cheaper for concessional patients and 25 per cent cheaper for general patients for the three-year tender period. This model, understood to have been preferred by the Department of Health and Ageing, was estimated as likely to save as much as \$830 million a year,

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- under the other proposal, the winning manufacturer would have six months in which they alone could offer patients a discount. The prices of other drugs in the therapeutic group would not be forced down to match. However, at the end of the six months, any other manufacturer that did drop its price to match would also be allowed to offer the discount. This option was estimated as likely to save up to \$370 million a year and was believed to be favoured by the Department of Industry.¹⁰

The Government was reported to have faced strong opposition from industry on these measures—both the originator and generic medicines industry each feared a reduction in revenues from each proposed system.¹¹ The originator industry was particularly keen to remove the link between the prices for originator and generic medicines and reportedly suggested a model to the Government that protects the price of originator medicines from price cuts to generics (reportedly similar in some respects to the model favoured by the Department of Industry).¹² According to industry representative body, Medicines Australia, this model was expected to save the Government around \$200 million per year.¹³

Basis of policy commitment

Of the four options outlined above, the PBS reform model announced in November 2006 bears most similarity to that proposed by the medicines industry (in that it separates pricing arrangements for medicines still under patent and medicines for which generics have become available). It is important to note that the Government provides no information on alternative pricing reform models it may have considered in either the Explanatory Memorandum or Minister's Second Reading Speech. The Explanatory Memorandum states that, on the advice of the Office of Best Practice Regulation, no Regulation Impact Statement is required.¹⁴ This makes it difficult to evaluate the rationale for the measures in this Bill in relation to other possible approaches and to get a clearer sense of the Government's purpose in introducing the Bill.

The main elements of the package are contained in this Bill and are described in detail in the Explanatory Memorandum and the Minister for Health and Ageing's Second Reading Speech. According to the Minister, the reforms establish 'structural changes to the pricing of medicines to achieve good value for listed medicines, while delivering long term savings to support the continued listing of cost-effective medicines into the future'.¹⁵

In brief, the purpose of the separate formularies is to enable the Government to achieve savings in the price it pays for PBS medicines without forcing price cuts on single brand medicines (for which there may be no suitable alternatives). Currently, as a result of what is known as 'reference pricing', the prices of PBS drugs that provide similar health outcomes are linked. Under this policy, the lowest priced brand or drug sets the benchmark price (the price the Government will pay for the drug) for either the other brands of that drug or the other drugs within the same therapeutic group.

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The problem the Government is seeking to address through this Bill is that reference pricing does not distinguish between single brand medicines and those with multiple brands operating in a competitive environment. Due to the more competitive environment, multiple brand medicines are frequently sold at a discounted price to pharmacies by suppliers (that is, at a price lower than that which the Government has agreed to pay). On the other hand, single brand medicines tend not to be offered to pharmacists at a discount rate. However, the effect of reference pricing has been to force price reductions on *both* multiple and single brand medicines. According to the Government, this situation creates financial difficulties for suppliers and creates the risk of withdrawal of particular drugs from the Schedule.

The division of the Schedule into separate formularies means that the Government can implement mandatory price reductions and hence make savings on the cost of the PBS which do not directly impact on single brand medicines. As F1 medicines, these will not be subject to any mandatory price reductions. On the other hand, F2 medicines will be subject to the following price reduction measures as a result of this Bill:

- a minimum 12.5 per cent price reduction on the price of any new bioequivalent (i.e. generic) brand of a medicine that lists on the PBS, as well as any existing brands of that medicine/those in the same therapeutic group that share the same manner of administration as the new brand (though not if they have previously taken a 12.5 per cent reduction). This legislates for a policy (discussed above) that was originally introduced without legislation in 2005
- a price reduction of 2 per cent per year for three years (from 1 August 2008) for 'low competition' F2 medicines (F2A)
- a one-off price reduction of 25 per cent on 1 August 2008 for 'high competition' F2 medicines (F2T), and
- mandatory price reductions in those cases where it is found that the difference between the price paid by a pharmacy for a medicine and the price approved by the Government is 10 per cent or more.

The latter measure appears to be specifically aimed at achieving savings from discounts provided to pharmacists by suppliers. It will be facilitated by the introduction of mandatory price disclosure for F2 medicines.

The Bill also introduces provisions ensuring that suppliers of a new bioequivalent medicine on the PBS and suppliers of existing brands that offer price reductions are required to guarantee the supply of these brands. The period to be mandated is 24 months or until another new brand of the medicine is listed or until a further price reduction is offered in relation to the medicine. There have been several recent cases in which a generic medicines company has been given a PBS listing (thereby triggering the mandatory 12.5 per cent price reductions described above) but has been unable to supply

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at the listing date.¹⁶ This means that rival suppliers are subject to a price reduction despite the absence of any new competitor medicine.

Finally, the Bill includes provisions for medicines which the Government believes may require alternative pricing arrangements (certain combination medicines and certain formulations that serve the particular needs of a subpopulation, such as oral solutions for paediatric or geriatric patients). These provisions have been added to the package following Government discussions with industry.¹⁷

Position of significant interest groups/press commentary

Stakeholder groups such as Medicines Australia, the Pharmacy Guild and the Australian Medical Association have indicated their general support for the reforms in this Bill.¹⁸

Concerns about the reform package have been raised by some industry groups (such as the Generic Medicines Industry Association) and commentators. These concerns include:

- the package does not include financial or other incentives for consumers to use generic medicines
- by creating separate formularies, the reforms may erode the effectiveness of the reference pricing system (a central component of the PBS aimed at promoting value for public money invested in the system)
- the protection of F1 medicines from mandatory price cuts may encourage 'evergreening' (filing patents for 'new uses' of a drug towards the end of a patent) as a tactic to delay the introduction of generic versions of medicines coming off patent, and
- price disclosure arrangements may erode the profits of Australian generic drug manufacturers and pharmacists.¹⁹

The theme in common to these criticisms is that the reforms does not do enough to facilitate (and indeed may lead to the erosion of) the development of the Australian generic medicines sector. A strong generics sector is seen by many commentators as essential to increased price competition in the Australian medicines sector, reduced costs to Government and hence the future sustainability of the PBS. As such, some commentators have predicted that the reforms in the Bill may actually increase the cost of the PBS over the longer term.²⁰

This claim has been rejected by the medicines industry peak body, Medicines Australia.²¹ Chief Executive of Medicines Australia, Ian Chalmers, has argued that PBAC oversight of applications for listing will continue to ensure that the Government and consumers 'won't pay more for new medicines than they would under the current system'.²²

Financial implications

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The Explanatory Memorandum to the Bill does not provide a figure for the financial implications of the Bill. Rather, it provides a figure for the financial impact of the PBS reform package as a whole. This is estimated at savings of \$580.4 million between 2006-07 and 2010-11. According to the Minister, savings from the reforms can be expected to grow to \$3 billion over the next ten years.²³

Main provisions

Item 1 inserts an explanation that a prescription for the supply of a pharmaceutical benefit is a reference to a prescription written in accordance with existing subsections 88(1) or (1A).

Items 2 -27 insert definitions into section 84 of the Act to provide definitions for concepts and measures being implemented in the Bill. Section 84 provides the interpretations guide for Part VII of the Act, which is the Part dealing with pharmaceutical benefits.

Of note is the new definition of ‘pharmaceutical benefit’ which currently means ‘a drug or medicinal preparation in relation to which, by virtue of section 85, this Part applies’. This is replaced by a definition that refers to the processes set out in section 85. There must be a declaration under subsection 85(2) in relation to a drug or medicinal preparation for there to be a pharmaceutical benefit. As explained in the [Explanatory Memorandum](#):

If there are no other relevant determinations, the pharmaceutical benefit is the drug. However:

- if there is also a determination under subsection 85(3) in relation to a form of the drug, the pharmaceutical benefit is the drug in that form;
- if in addition, there is also a determination under subsection 85(5) in relation to a manner of administration of that form of the drug, the pharmaceutical benefit is the drug in that form with that manner of administration; and
- if, in addition, there is also a brand determination under subsection 85(6), the pharmaceutical benefit is that brand of the drug in that form with that manner of administration.

Related to this definition is the new concept of a ‘pharmaceutical item’ in **new section 84AB**. If there is a declaration under section 85(2) in relation to a drug, and a determination under subsection 85(3) and **new subsection 85(5)** that a particular drug is in a particular form with a particular manner of administration, the pharmaceutical item is available under the PBS.

Also inserted into section 84(1) is the definition of ‘responsible person’. Under **new section 84AF** the Minister may by legislative instrument determine that a person is the

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responsible person for a brand of a pharmaceutical item if the person is or will be the supplier of the brand to wholesalers, or if none are involved, to approved pharmacists, and the brand of the pharmaceutical item is a listed brand. **New paragraph 84AF(1)(c)** ensures that the same person must be the responsible person for all pharmaceutical items that have that brand.

New sections 84AC and 84AD are the key sections in the Bill relating to providing the mechanisms for placing drugs on the two formularies, F1 and F2, and listed drugs in Part A or Part T of F2.

The criteria for F1 are set out in **new subsections 85AB(4)-(5)** as follows:

- (a) there are no listed brands of pharmaceutical items that:
 - (i) have the drug; and
 - (ii) are bioequivalent;
 - (b) there are no listed brands of pharmaceutical items that:
 - (i) have another listed drug that is in the same therapeutic group as the drug; and
 - (ii) are bioequivalent;
 - (c) the drug was not on F2 on the day before the determination under subsection (1) comes into force.
- (5) This section does not apply to the drug if:
- (a) the drug is in a combination item; and
 - (b) there are no listed brands of combination items that:
 - (i) have the drug; and
 - (ii) are bioequivalent.

New section 85AD allows the Minister and the responsible person to reach agreement on an amount that is taken to be the appropriate maximum price for sales of the brand of the pharmaceutical item to ‘approved pharmacists’. In the absence of agreement, the Minister may, by legislative instrument, determine the appropriate maximum price (**new subsection 85B(2)**). **Proposed subsection 85B(5)** allows the Minister to determine, by legislative instrument, the circumstances in which a special patient contribution may be paid by the Commonwealth rather than the patient. The Explanatory Memorandum states:

This will ensure that in the very special circumstances where other brands of that item, or other items, are not suitable for a particular patient, the patient may obtain the

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particular brand of the item without having to pay the additional special patient contribution.²⁴

The difference between the price claimed by the responsible person, and the price determined by the Minister forms the basis for special patient contribution.

Item 81 inserts **new Divisions 3A, 3B and 3C** into Part VII of the Act, namely **new sections 99AC to 99AEL**.

Division 3A governs the price reductions that are to apply to listed brands of pharmaceutical items. **Subdivision B** will require a 12.5% reduction for new brands of pharmaceutical items that are not combination items. **Subdivision C** sets out the requirements for price reductions for combination items. **Subdivision D** provides for price reductions for pharmaceutical items flowing on from the 12.5% reductions required under Subdivision B and arising if a pharmaceutical item has a drug on F2 on a particular day. The details of the amendments are explained at pages 10-15 of the Explanatory Memorandum.

Division 3B makes provision for the price disclosure requirements imposed on a responsible person in relation to the supply of brands of pharmaceutical items including the consequences if a person fails to comply with these requirements. An offence is created under **new section 99ADF** carrying a penalty of \$33,000 for a corporation²⁵ and \$6,600 for an individual. The details of the amendments are explained at pages 15-20 of the Explanatory Memorandum.

Division 3C governs the guarantee of supply of certain brands of pharmaceutical items including the Minister's powers in the event that a responsible person fails to supply or is unable to supply the guaranteed brand of the guaranteed item. Under **new section 99AEH** the Minister may:

- delist the brand that was subject to the guarantee of supply requirements
- delist any other brand for which the responsible person was responsible; and
- refuse to list any new brand of any pharmaceutical item for which the responsible person is responsible.

The responsible person is obliged to notify the Minister if the person forms the belief that he or she may not be able to supply a brand or in the event that this failure has occurred, then as soon as practicable after the failure occurs **new section 99AEG**. An offence is created in the event of failure to notify the Minister under this section. According to the explanatory statement, the penalty will be \$33 000 for a corporation and \$6 600 for an individual.

Part 2 of the bill makes the transitional amendments to ensure application and operation of declarations and determinations.

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Concluding comments

This Bill implements key aspects of the PBS reform package announced in November 2006. Broadly, the purpose of the Bill is to introduce new arrangements for the determining the price the Government pays for medicines listed on the PBS. The main changes are:

- the division of the PBS into two formularies (one for single brand medicines (F1) and one for multiple brand medicines (F2))
- the introduction of a range of mandatory price reduction measures for F2 medicines, and
- the introduction of a system of mandatory price disclosure to ensure that the price the Government pays for PBS medicines more closely reflects the price paid by pharmacists.

This amounts to a substantial restructuring of pricing arrangements for the PBS. The Government argues that the purpose of this is to ensure value for money for medicines listed on the PBS and support the future sustainability of the PBS.

As discussed above, it appears that this is one of several models for PBS pricing reform the Government has examined over the past few years. This particular model, unlike others under consideration, appears to be generally supported by stakeholders such as the industry peak body, Medicines Australia.

A number of concerns have been raised in relation to the Bill by the Generic Medicines Industry Association and industry commentators. The main thrust of their concerns is that the reforms do not do enough to advance (and in fact may damage) the development of a generic medicines industry in Australia. This, they argue, may have the effect of increasing the cost of the PBS over the longer term. Such an outcome would be at odds with the stated objective of the Bill. Medicines Australia, has rejected the possibility that the changes would lead the Government and consumers to pay more for new medicines.

This Bills Digest has raised a number of issues that Members and Senators might wish to consider in their deliberation on this Bill, including:

- what are the advantages of this particular model of pricing reform over others that the Government may have considered?
- what is the likely impact of the reforms on reference pricing?
- what is the likely impact of the reforms on the generic medicines industry?
- is the Government doing enough to enhance the role of generic medicines in Australia (something that many commentators believe is necessary to ensure the future sustainability of the PBS)?

The Government expects to achieve cost savings to the PBS both in the short and long term as a result of this Bill. A key issue, though, is whether additional measures and/or

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more far-reaching reforms might have made added further to the sustainability of the PBS. A further issue is whether the introduction of two tiers of listing (via two formularies) might have the unintended consequence of disadvantaging the generic medicines sector and perhaps of eroding the objective of securing the PBS into the future.

Endnotes

1. M Biggs, '[The Pharmaceutical Benefits Scheme—an overview](#)', *E-Brief*, Parliamentary Library, Canberra, 2002-03.
2. [Strengthening Your PBS—Preparing for the Future](#), Department of Health and Ageing.
3. [Expenditure and Prescriptions twelve months to 30 June 2006](#), Department of Health and Ageing.
4. *ibid.*
5. *ibid.*
6. [Australian Government 2007-08 Health and Ageing Portfolio Budget Statements](#), p. 73.
7. J. Breusch, 'Drug pills easier to swallow', *Australian Financial Review*, 3 April 2007.
8. See, for example, M. Metherell, 'Plan takes from drug companies to give to the elderly', *Sydney Morning Herald*, 2 October 2004.
9. 'Drug companies concerned over increased premiums, leading to higher prices for consumers', PM—ABC Radio, 25 January 2005.
10. See A. Stafford, 'PBS cost-cutting options go to cabinet', *Australian Financial Review*, 11 January 2006; S. Dunlevy, 'PBS overhaul halves drug bill', *Daily Telegraph*, 3 February 2006.
11. A. Stafford, 'PBS cost-cutting options go to cabinet', *op. cit.*
12. A. Stafford, 'Industry says PBS option good medicine', *Australian Financial Review*, 3 February 2006.
13. *ibid.*
14. Explanatory Memorandum, p. 2.
15. Hon Tony Abbott MP, Minister for Health and Ageing, National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2007: Second Reading Speech, House of Representatives, *Debates*, 24 May 2007, pp. 1-2.
16. 'Minister hopes Ranbaxy is one-off', *Pharma in Focus*, 28 August 2006.
17. 'PBS reform Bill springs surprises', *Pharma in Focus*, 28 May 2007.
18. T. Abbott, Second Reading Speech, *op. cit.*, p. 2.

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19. See for example T. Faunce and A. Searle, 'Review of drugs changes should be priority', *Canberra Times*, 15 May 2007; L. Russell, 'Reforms to pharmaceutical costs won't benefit consumers', *Age*, 8 May 2007.
20. *ibid.*
21. I. Chalmers, 'Pharmacy industry is not a bogey man', *Canberra Times*, 22 May 2007.
22. *ibid.*
23. T. Abbott, Second Reading Speech, *op. cit.*, p. 2.
24. Explanatory Memorandum, p. 9.
25. By operation of the *Crimes Act 1914*, subsection 4B(3).

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