

COMPILATION OF  
THE FOURTH COMMUNITY PHARMACY  
AGREEMENT  
BETWEEN  
THE COMMONWEALTH OF AUSTRALIA  
AND  
THE PHARMACY GUILD OF AUSTRALIA

This Agreement comprises:  
Principal Agreement of 16 November 2005  
Amendments of 2 March 2007  
Amendments of 1 August 2007

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- g. The parties understand that the Pharmaceutical Society of Australia, whilst not a signatory to this Agreement, will be an active participant in those areas of this Agreement that are related to professional practice.

## **1.2 Amendments to the Fourth Community Pharmacy Agreement**

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- A. On 16 November 2005, the parties entered into the Fourth Community Pharmacy Agreement (the Agreement) for the purpose, among other matters, of agreeing the manner in which the Commonwealth price is to be ascertained for the purpose of payments to approved pharmacists under Part VII of the National Health Act 1953 and of agreeing other payments.
- B. On 16 November 2006 the Minister for Health and Ageing announced changes to the Pharmaceutical Benefits Scheme (the PBS). The Government has produced a fact sheet outlining its proposed reforms which it has provided to the Guild for its information and which is annexed to this Agreement for the information of the Guild. It is the intention of the Government to update this fact sheet if necessary when the amendments to the Act required to implement the changes has come into effect.
- C. To assist pharmacists adjust to the changes to the PBS, the Government has agreed with the Guild a number of initiatives to restructure pharmacist remuneration including:
  - a. Adjustments to pharmacy mark-ups, including a \$70 mark-up for medicines priced above \$1,750;
  - b. An increased dispensing fee;
  - c. A 40 cent payment for each prescription processed using PBS Online; and
  - d. A \$1.50 (indexed) incentive for dispensing substitutable, premium free brands of PBS items.
- D. In addition to the above, the parties have also agreed amendments to the Agreement which include:
  - a. Additional funding of \$69 million (inclusive of indexation) over three years for the Community Service Obligation Funding Pool, to assist CSO Distributors in adjusting to the impact of the changes to the PBS.
  - b. Up to \$20 million in payments to software vendors to assist the accelerated implementation of PBS Online.

## **2. Principles and Objectives**

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- 2.1. Within the above context, the principles and objectives of this Agreement are to:
  - a. ensure a fair Commonwealth price is paid to approved pharmacists for providing pharmaceutical benefits while maximising the value to taxpayers by encouraging an effective and efficient community pharmacy network;

- b. ensure that the Programs target areas of need in the community including continued improvement in community pharmacy services provided to Aboriginal and Torres Strait Islander people;
- c. ensure transparency and accountability in the expenditure of the funds which the Commonwealth has appropriated for the Programs to improve the health outcomes for the Australian community;
- d. maintain a stable and viable community pharmacy sector so that pharmacists can continue to provide quality pharmacy services to the Australian community;
- e. maintain a co-operative relationship between the Commonwealth and the Guild; and
- f. ensure the Location Rules work for the benefit of the Australian community including increased access to community pharmacies for persons in rural and remote areas of Australia.

### **3. Structure**

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3.1. This Agreement consists of 6 Parts.

3.2. The 6 Parts are:

- a. **Part 1: Introduction** -The Introduction includes preliminary matters including setting out the context, the objectives and the term of the Agreement and matters which apply to all parts of the Agreement eg the definitions and the role of the Agreement Consultative Committee and Professional Programs and Services Advisory Committee.
- b. **Part 2: Commonwealth price** -This Part documents the agreement reached between the Commonwealth and the Guild in relation to the manner in which the Commonwealth price is to be ascertained. This Part represents an agreement between the parties in accordance with s.98BAA (1) of the Act.
- c. **Part 3: Other Payments** - This Part sets out the intention of the parties in relation to the Community Service Obligation (CSO) Funding Pool and other payments.
- d. **Part 4: Location Rules** - This Part sets out the amendments to the Location Rules which the Minister has approved and which it is intended will become the basis for a variation to the determination which the Minister must make under s.99L of the Act.
- e. **Part 5: Professional Pharmacy Programs and Services** - This Part deals with the professional pharmacy programs and services which the Department will administer during the term of the Agreement. It sets out the governance and accountability framework within which the Commonwealth

is required to operate in administering the funds appropriated by the government for these Programs.

- f. **Part 6:** This Part consists of miscellaneous matters.

#### 4. **Definitions**

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<b>Act</b>	means the <i>National Health Act 1953</i> .
<b>ACPA</b>	means the Australian Community Pharmacy Authority set up under Division 4B of the Part VII of the Act.
<b>Agreed price</b>	means the agreed price for a pharmaceutical and repatriation benefit under s.84C as determined by the Minister under s.84C(7) and ascertained in the manner set out in s.84C(8) of the Act.
<b>Agreement</b>	means the Fourth Community Pharmacy Agreement which the parties entered into on 16 November 2005.
<b>Agreement Consultative Committee</b>	Agreement Consultative Committee is the committee set up under clause 7.
<b>Amending Agreement</b>	means the amending agreement to vary the Agreement
<b>Approved pharmacist</b>	means a pharmacist approved under s.90 of the Act.
<b>Approved Supplier</b>	means an Approved Pharmacist, an approved medical practitioner or an approved hospital authority as defined in subsection 84(1) of the <i>National Health Act 1953</i>
<b>Commonwealth price</b>	means an amount worked out in accordance with a determination in force under s.98B(1) to determine the amount that the Commonwealth pays to approved pharmacists in relation to the supply of pharmaceutical benefits.
<b>CSO</b>	means the Community Service Obligation Funding Pool which is described in clause 23.
<b>Department</b>	means the Department of Health and Ageing.
<b>FMA Act</b>	means the <i>Financial Management and Accountability Act 1997</i> .
<b>Funds</b>	means the money approved by the government for expenditure on the Programs during the term of the Agreement and includes Funds which were appropriated for Programs under the Third Community Pharmacy Agreement but remain unspent under that Agreement.

<b>Location Rules</b>	means the rules determined by the Minister under s.99L of the Act subject to which the ACPA makes recommendations under the Act in relation to approval of pharmacists in respect of particular premises.
<b>Minister</b>	means the Minister who administers the Act.
<b>PBS</b>	means the Pharmaceutical Benefits Scheme established under Part VII of the Act.
<b>Pharmaceutical benefit</b>	means a drug or medicinal preparation in relation to which, by virtue of s.85 of the Act, Part VII applies.
<b>Professional Programs and Services Advisory Committee</b>	means the committee set up under clause 8 to advise the Minister on aspects of the Programs.
<b>Programs</b>	means the professional pharmacy programs and services set out in Part 5.
<b>Tribunal</b>	means the Pharmaceutical Benefits Remuneration Tribunal established under s.98A of the Act.

## **5. Interpretation**

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- 5.1. In this Agreement, unless the contrary intention appears, a word or expression not otherwise defined but which is used in the Act, shall be taken to have the same meaning as in Part VII of the Act.

## **6. Duration of Agreement**

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- 6.1. This Agreement commences on 1 December 2005 and terminates on 30 June 2010.
- 6.2. The parties agree that the provisions of clauses 14.2, 14.4, 20.1, 21.4 and 23.6b. will continue till 30 June 2011 and that they will ensure that these provisions are reflected in any new agreement which comes into effect before that time.

## **7. Agreement Consultative Committee**

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- 7.1. The Agreement Consultative Committee will be the mechanism for consultation between the parties on implementation of this Agreement, including issues relating to Approved Pharmacists' payments and Location Rules and consideration of other matters as set out in Part 6 of this Agreement .
- 7.2. The Committee will comprise a maximum of four members from the Guild and four members from the Department.

- 7.3. Terms of Reference for the Committee, including meeting arrangements and operating rules, will be developed by the Guild and the Department.

## **8. Professional Programs and Services Advisory Committee**

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- 8.1. In order to ensure transparent, contestable, merit based allocation of funds within an accountability framework, a Professional Programs and Services Advisory Committee will operate under the Fourth Agreement.
- 8.2. The Committee will consider issues relating to the Professional Pharmacy Programs and Services and provide advice and recommendations directly to the Minister. This representational Committee will include:
- a. five members appointed by the Guild (including four pharmacists); and
  - b. five members appointed by the Minister, comprising one member of the Pharmaceutical Society of Australia and one other pharmacist, with the remaining three members drawn from individuals and organisations with an interest in the programs being funded, including doctors, allied health professionals, aged care professionals, consumers and representatives from the indigenous community.
- 8.3. The Committee Chair will be appointed by the Minister and selected from the 10 committee members.
- 8.4. The Department will not be represented on the Committee but will provide secretariat support to the Committee.
- 8.5. The function of the Committee will be to provide advice to the Minister on:
- a. the funding of the projects and management responsibilities for projects and programs under the Professional Pharmacy Programs and Services;
  - b. the development of policy objectives, eligibility criteria and performance outcome measures for programs to be funded under the Professional Pharmacy Programs and Services;
  - c. monitoring the outcome of programs funded under the Professional Pharmacy Programs and Services; and
  - d. any other function that may be agreed between the Minister and the Guild.
- 8.6. The Terms of Reference for the Committee will reflect the functions described in clause 8.5 and will be developed by the Guild and the Department and will be subject to the Minister's approval. The Terms of Reference will also set out the responsibilities, accountabilities and decision making processes for the Committee.

## **PART 2-COMMONWEALTH PAYMENTS TO PHARMACISTS**

### **9. What Part 2 does**

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- 9.1. Part 2 constitutes an agreement between the Guild and the Minister as referred to in s.98BAA of the Act which sets out the manner in which the Commonwealth price is to be ascertained and which the Tribunal must give effect to in determining the Commonwealth price.

### **10. Commencement of obligations under Part 2**

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- 10.1. The obligations under Part 2 will commence on 1 December 2005 and continue until 30 June 2010.

### **11. Purpose of Part 2**

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- 11.1. The purpose of Part 2 is to:
- a. describe the basis for, and calculation of, the Commonwealth price and variations to that price that may occur over the life of the Agreement; and
  - b. ensure that all components which make up the Commonwealth price are clearly documented so that there is certainty for all approved pharmacists.

### **12. Agreed Basis of the Commonwealth price**

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- 12.1. The Commonwealth price has been set based on a formula which comprises the ex-manufacturer price plus allowances for the supply of PBS medicines over and above that price.
- 12.2. In agreeing to a Commonwealth price for a particular medicine the Commonwealth includes allowances for:
- a. the cost to the pharmacist (approved price to pharmacist), which includes two components:
    - A. production of the medicine (price ex manufacturer);
    - B. wholesale distribution of the medicine;
  - b. the handling and storage of medicines by the pharmacy; and
  - c. the pharmacist's specialised skills in dispensing the medicines.

### **13. Patient contribution**

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- 13.1. The specific amounts of patient contributions for PBS medicines are as set out in the Act and pharmacists are required by the Act to charge those amounts.

## 14. Commonwealth price and other payments

14.1. The components of the remuneration including the Commonwealth price are as set out in clause 14.2 and as described in the Schedule to this Agreement.

14.2.

<b>Type of Payment</b>	<b>Basis of Payment</b>	<b>Date of Effect</b>	<b>Value</b>
<i>Wholesale mark-up<sup>1</sup></i>	<i>(mark-up on ex-manufacturer's price)</i>		
	<i>Up to and including \$930.06</i>	<i>1 July 2006</i>	<i>7.52%<sup>2</sup></i>
	<i>Over \$930.06</i>		<i>\$69.94</i>
<i>Pharmacy Mark-up<sup>3</sup></i>	<i>(mark-up on Approved Price to Pharmacist)<sup>4</sup></i>		
	<i>Up to and including \$180.00</i>	<i>1 July 2006</i>	<i>10.0%</i>
	<i>Between \$180.01 and \$450.00</i>		<i>\$18.00</i>
	<i>Between \$450.01 and \$1000.00</i>		<i>4.0%</i>
	<i>Over \$1000.00</i>		<i>\$40.00</i>
<i>Dispensing Fee (Ready Prepared)</i>		<i>1 Dec 2005<sup>5</sup></i>	<i>\$4.94</i>
		<i>1 July 2006<sup>6,7</sup></i>	<i>\$5.15</i>
<i>Special Handling Fee<sup>8</sup></i>	<i>Dangerous drug</i>	<i>1 July 2006</i>	<i>\$2.71</i>
	<i>Extemporaneously prepared</i>		<i>\$2.04</i>

14.3. The payments set out in clause 14.2 above, excluding the 1 August 2008 addition of 15 cents, result in an agreed \$350 million reduction in payments to pharmacy than would otherwise have been made over the forward estimates

<sup>1</sup> Fixed for the life of the Agreement.

<sup>2</sup> Equates to a 7.0% wholesale margin.

<sup>3</sup> Pharmacy Mark-up until 31 July 2008. From 1 August 2008 there will be a new pricing structure, as set out in clause 14.4.

<sup>4</sup> Approved Price to Pharmacist (includes price ex-manufacturer and wholesale mark-up).

<sup>5</sup> Dispensing fee includes payments for CMI, IME and for reinstatement of the full value of indexation applicable from 1 July 2005 (but which was reduced by the PDP shavings from Third Agreement).

<sup>6</sup> 1 July 2007 indexed by WCI9 per annum (or its replacement index). 1 August 2007 the dispensing fee will be increased by \$0.12. 1 July 2008 indexed by WCI9 per annum (or its replacement index). 1 August 2008 the dispensing fee will be increased by \$0.15. 1 July 2009 indexed by WCI9 per annum (or its replacement index). 1 July 2010 indexed by WCI9 per annum (or its replacement index).

<sup>7</sup> A review of estimate differences, to be completed by end of August 2007, will determine the precise quantum of any fee increase (if required), subject to the agreement of the Parties.

<sup>8</sup> These fees are payable in addition to the base ready prepared dispensing fee.

period for the distribution, supply and dispensing of prescriptions for PBS medicines and medicines listed on the Schedule of Pharmaceutical Benefits provided under the Repatriation Pharmaceutical Benefits Scheme (RPBS) over the life of the Agreement. The forward estimates payments to pharmacy are derived from the prescription volume estimates set out in clause 15.1.

- 14.4. From 1 August 2008 the Pharmacy Mark-up on all PBS/RPBS items will be as follows:

<b><i>Pharmacy Mark-up<sup>9</sup></i></b>	<b><i>Mark-up on Approved Price to Pharmacist<sup>10</sup></i></b>	<b><i>Date of Effect</i></b>	<b><i>Value</i></b>
	<i>Up to and including \$30.00</i>	<i>1 August 2008</i>	<i>15%</i>
	<i>Between \$30.01 and \$45.00</i>		<i>\$4.50</i>
	<i>Between \$45.01 and \$180.00</i>		<i>10%</i>
	<i>Between \$180.01 and \$450.00</i>		<i>\$18.00</i>
	<i>Between \$450.01 and \$1750.00</i>		<i>4%</i>
	<i>Over \$1750.00</i>		<i>\$70.00</i>

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<sup>9</sup> see footnote 3 above

<sup>10</sup> see footnote 4 above

## 15. Risk Share Arrangements

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- 15.1. This Agreement is based on the following estimates for PBS and RPBS prescription volumes:

	2005-06 <sup>11</sup>	2006-07 <sup>11</sup>	2007-08 <sup>11</sup>	2008-09 <sup>11</sup>	2009-10 <sup>11</sup>
PBS & RPBS Prescription Volumes (m) <sup>12</sup>	186.208	199.416	209.282	218.847	228.333

- 15.2. Clause 15.1 is amended by replacing the PBS and RPBS Prescription Volumes for the years 2006-07 to 2009-10 by the following Prescription Volumes for those years:

	2006-07 <sup>13</sup>	2007-08 <sup>13</sup>	2008-09 <sup>13</sup>	2009-10 <sup>13</sup>
PBS & RPBS Prescription Volumes (m) <sup>14</sup>	196.237	206.907	216.545	226.050

- 15.3. The parties agree that adjustments to the remuneration arrangements set out in clause 14.2 are appropriate if the actual movement in community pharmacy prescription volume varies beyond the threshold as described at clause 15.4.
- 15.4. The parties therefore agree to a risk sharing arrangement under which remuneration is adjusted if prescription volumes are less than 95% or over 105% of the forecast forward estimates (as set out in clause 15.2) for any particular year.
- 15.5. For every PBS prescription above or below this threshold (as described in clause 15.4), payments (retail mark-up + dispensing fee), for those scripts (based on the average across all scripts) will be shared 50:50 between pharmacy and the Commonwealth, via a reduction/increase in the dispensing fee for the following year.

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<sup>11</sup> Forward Estimate Prescription Volume Period 1 July to 30 June

<sup>12</sup> Includes PBS medicines and medicines listed on the Schedule of Pharmaceutical Benefits provided under the Repatriation Pharmaceutical Benefits Scheme (RPBS)

<sup>13</sup> Forward Estimate Prescription Volume from clause 15.1 re-phased for the period 1 April to 31 March

<sup>14</sup> Includes PBS medicines and medicines listed on the Schedule of Pharmaceutical Benefits provided under the Repatriation Pharmaceutical Benefits Scheme (RPBS)

15.6. Reduction in the dispensing fee will be calculated as follows:

Number of scripts above the threshold	=	Actual volume for year Y– 1.05 x Forecast volume for year Y
Multiplied by the average payment	x	Ave (MU + DF) for year Y
Multiplied by pharmacy risk share factor	x	50%
Divided by the forecast volume for the following year	÷	Forecast volume for year Y+1
	=	DF variation

The Dispensing fee for the next year will therefore be:

Dispensing fee for this year		DF for year Y
Plus indexation		DF for year Y x (1+indexation factor)
Minus the variation in the dispensing fee		DF variation

15.7. Increase in dispensing fee will be calculated as follows:

Number of scripts below the threshold		0.95 x Forecast volume for year Y - Actual volume for year Y
Multiplied by the average payment		Ave (MU + DF) for year Y
Multiplied by pharmacy risk share factor		50%
Divided by the forecast volume for the following year		Forecast volume for year Y+1
	=	DF variation

The Dispensing fee for the next year will therefore be:

Dispensing fee for this year		DF for year Y
Plus Indexation		DF for year Y x (1+indexation factor)
Plus the variation in the dispensing fee		DF variation

For the purposes of clauses 15.5 and 15.6 **MU** means **pharmacy mark-up** and **DF** means **dispensing fee**.

- 15.8. Comparison between actual and estimated figures will be based on the 12 month period to 31 March in the relevant year ('the reference period').
- 15.9. The parties agree that the pharmacist dispensing fee as set out in clause 14.2 will be indexed annually by WCI9, or its replacement index as determined under the Government's revised industrial relations arrangements. The Government will apply the higher indexation factor between the WCI9 (as it applied prior to its replacement) and the replacement index.

## **16. Review of components of remuneration**

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- 16.1. The parties agree that the method of calculating any elements of the remuneration covered by Part 2 of the Agreement, and the level of that remuneration, may be varied by agreement in writing between the parties.

## **17. Dispute Resolution**

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- 17.1. The parties agree that any dispute which arises concerning this Part will be dealt with as follows:
- a. first, the party claiming that there is a dispute will send to the other a notice setting out the nature of the dispute;
  - b. secondly, the parties will try to resolve the dispute by direct negotiation within 20 working days;
  - c. if the dispute is not resolved within 20 days as set out in b., the parties will, within a further period of 28 days, refer the matter to the Tribunal for resolution;
  - d. the parties agree to adhere to a decision of the Tribunal made under c. above;
  - e. if the parties resolve the dispute they shall, if required, present the agreement reached between them to the Tribunal for an appropriate determination; and
  - f. each party will meet any costs which it may incur as a result of the dispute.

## **18. Waiver**

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- 18.1. A waiver of any provision of Part 2 must be in writing.
- 18.2. No waiver of an obligation under Part 2 shall operate as a waiver of another breach of the same or any other condition.

## **PART 3-OTHER PAYMENTS**

### **19. Other changes**

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- 19.1. Where, during the life of the Fourth Agreement, the Government has taken a decision as part of a health related budget initiative that has a significant and sustained impact on the viability of community pharmacy, the Government will consult in good faith with the Guild about that impact.
- 19.2. Both parties will take into account the cost of any identifiable and quantifiable administrative impost/increase (above the present status quo) on pharmacies incurred during the life of the Agreement, that is directly attributed to an alteration to the *National Health Act 1953* or its subordinate legal instruments, or the introduction of a Commonwealth health related budget initiative external to the Agreement, and that is required to be implemented by community pharmacy.

### **20. Concessional Entitlement Validation Payments (CEV) and PBS Online Payments**

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- 20.1. The Commonwealth agrees to pay Approved Suppliers a payment of 40 cents per PBS prescription processed through PBS Online. The Payment for PBS Online will commence from 1 July 2007 and is separate from, and in addition to, remuneration set out in clauses 14.2 and 14.4.
- 20.2. To assist Approved Pharmacists in meeting their obligations under Section 87 (3A) of the Act the Commonwealth agrees to pay a Concessional Entitlement Validation payment of 10 cents per PBS Concessional Prescription processed by pharmacies until 30 June 2007. The remuneration for Concessional Entitlement Validation is separate from, and in addition to, pharmacy remuneration as set out in clauses 14.2 and 14.4
- 20.3. Approved Pharmacists that have lodged a valid "Online Claims for PBS Pharmacy Participation Agreement" form by 1 July 2007 will continue to receive the 10 cent Concessional Entitlement Validation payment until PBS Online is operational in those Approved Pharmacists or 31 December 2007, whichever is the sooner. Those Approved Pharmacists that have not lodged a valid "Online Claims for PBS Pharmacy Participation Agreement" form by 1 July 2007 will receive no further payments for Concessional Entitlement Validation from that date.
- 20.4. Until 31 December 2007, non online pharmacies will continue to receive a warning from Medicare Australia where patients without a current concessional entitlement are charged at the concessional rate. The exception will be payments in respect of patients who have not had a valid concessional entitlement in the 12 month period preceding the date of supply. From

1 July 2007, these payments will be rejected and will need to be resubmitted as general benefits.

- 20.5. The parties agree that they will work together to identify ways to ensure that, after 31 December 2007, concessional benefits are paid only in respect of patients with a valid concessional entitlement. This work will recognise there are times when a non-online pharmacy may provide a concessional benefit to an ineligible patient after having taken all reasonable steps to satisfy themselves that on the date of supply the patient was entitled to concessional benefits.

## **21. Additional Charges**

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- 21.1. For ready prepared and extemporaneously prepared items priced below the maximum general patient contribution as defined in the Act, approved pharmacists will be able to charge the sum of:
- a. the Commonwealth price;
  - b. an additional patient charge which when combined with the Commonwealth price will equal the list or agreed price as referred to in subsection 84C(7);
  - c. a further additional patient charge amounting to 10% of the maximum general patient contribution plus 50 cents.
- 21.2 The additional patient charge referred to in clause 21.1(c) cannot be recorded on the prescription record form to accumulate towards the Safety Net Entitlement as defined in s.84C of the Act.
- 21.3 Approved pharmacists are to make patients aware of the charges described in clause 21.1(c) and of the fact that they are not Commonwealth initiated.

## **21.4 Premium Free Dispensing Incentive Payment**

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- 21.4a From 1 August 2008, a fee of \$1.50, indexed annually by WCI9 or its replacement, will be paid to Approved Suppliers<sup>15</sup> for each substitutable brand dispensed where a Premium does not apply. Substitutable products are those flagged as 'bioequivalent' with one or more other products in the Schedule of Pharmaceutical Benefits.
- 21.4b The dispensing incentive payment is not payable for General Pharmaceutical Benefits dispensed where the Commonwealth Price is less than or equal to the General patient contribution.

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<sup>15</sup> *all Approved Suppliers except approved hospital authorities located at a public hospital which has implemented pharmaceutical reforms under Section 21, Part 4 of the Australian Health Care Agreements 2003-2008*

- 21.4c The remuneration for dispensing a substitutable brand where a Premium does not apply is separate from, and in addition to, pharmacy remuneration as set out in clauses 14.2 and 14.4.

## **22. Highly Specialised Drugs Program**

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- 22.1 Where a community pharmacy provides pharmaceutical services to a private hospital which provides medicines under the Highly Specialised Drugs Program to eligible outpatients, that pharmacy will be eligible for remuneration for the provision of this service. The Commonwealth agrees that it will remunerate these approved pharmacies for the supply of Highly Specialised Drugs.

- 22.2 The parties agree that remuneration should be allocated for the dispensing of Highly Specialised Drugs for private hospitals on the following basis:

The ready prepared dispensing fee plus a mark-up calculated as follows:

- i. 10% for drugs with a price ex-manufacturer of less than \$40;
  - ii. \$4 for drugs with a price ex-manufacturer of between \$40 and \$100;
  - iii. 4% for drugs with a price ex-manufacturer of between \$100.01 and \$1000; and
  - iv. \$40 for drugs with a price ex-manufacturer of greater than \$1000.
- 22.3 These arrangements will be reviewed within the first year of the Agreement, as described at clause 37.

## **23. Community Service Obligation Funding Pool**

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- 23.1. The Commonwealth intends to establish a CSO Funding Pool of \$150 million per annum.
- 23.2. The CSO Funding Pool will be indexed annually on the same basis as the pharmacist dispensing fee set out in clause 14.2 and indexed with the same indices as for pharmacy remuneration as described in clause 15.8.
- 23.3. The purpose of the CSO Funding Pool is to ensure that:
- a. All community pharmacies are able to obtain timely supply of the full range of PBS medicines, irrespective of the size or location of the pharmacy, the breadth of the PBS product range, the cost of the PBS medicines, or the cost of their distribution and supply to pharmacy.
  - b. All Australians have timely access to the PBS medicines they require, regardless of the cost of the medicine, or where they live.

- 23.4. Payments from the CSO Funding Pool will be made to eligible wholesale distributors of PBS medicines, who meet specified service standards. The intention is to remunerate pharmaceutical wholesalers for the additional cost they incur in providing the full range of PBS medicines, available to wholesalers, as compared to those wholesalers who distribute and supply a lesser range of PBS products.
- 23.5. Wholesalers will be eligible to access the CSO Funding Pool if they can demonstrate they can meet specified service standards, including distribution and supply of the full range of PBS medicines generally within 24 hours. This includes medicines ordered in low volumes (including single units where required), and at least one benchmark priced product for each PBS line (where a benchmark priced product is available):
- a. to any pharmacy in Australia (National Full Line Wholesalers), or to any pharmacy in the State or Territory in which the wholesaler has a distribution centre (State Based Full Line Wholesalers); and
  - b. at a price to pharmacy at or below the approved price to pharmacist.
- 23.6a The initial value of the CSO Funding Pool will be \$150 million per annum (commencing 1 July 2006) indexed annually. This Funding Pool includes a separate allocation of up to \$5 million per annum (commencing 1 July 2006) in payments to State Based Full Line Wholesalers.
- 23.6b. From 1 August 2008 an additional \$69 million (inclusive of indexation) will be added to the CSO Funding Pool as set out in the table below. This funding pool includes a separate allocation of funds to State Based Full Line Wholesalers.

<b>Year</b>	<b>National Wholesalers</b>	<b>State Based Full Line Wholesalers</b>	<b>Total</b>
2008-09	\$21.34m	\$0.66m	\$22m
2009-10	\$22.31m	\$0.69m	\$23m
2010-11	\$23.28m	\$0.72m	\$24m

- 23.7. Funding for State Based Full Line Wholesalers within their part of the total CSO Funding Pool will be apportioned across all States and Territories according to relative freight costs (or other factor, as agreed between eligible wholesalers and the Commonwealth).
- 23.8. State Based Full Line Wholesalers will not be entitled to a greater amount per PBS medicine supplied than National Full Line Wholesalers.

- 23.9. Full Line National Wholesalers will share in the balance of the CSO Funding Pool which will include that part of the Funding Pool separately allocated for State Based Full Line Wholesalers (as described at clause 23.7) that is unpaid at the end of each month.
- 23.10. Eligible National and State Based Full Line Wholesalers will provide data on the actual volume of sales of PBS medicines to all pharmacies, including low volume PBS medicines, and PBS medicines supplied to rural and remote pharmacies, on a monthly in-arrears basis.
- 23.11. Payments from the CSO Funding Pool will be made monthly, in arrears, based on each wholesaler's actual monthly share of the actual volumes of PBS medicines supplied to all pharmacies.
- 23.12. For the purposes of the CSO Funding Pool, references to actual sales and volumes relate to Schedule of Pharmaceutical Benefits items only.
- 23.13. Eligible National and State Based Full Line Wholesalers will be paid a share of the CSO Funding Pool only if actual sales to rural and remote pharmacies and actual sales of low-volume PBS medicines are in line with total industry data. This will be validated on an annual basis in the context of a year of industry data provided by eligible wholesalers on actual sales volumes of PBS low volume medicines, and PBS medicines supplied to rural and remote pharmacies.
- 23.14. Where eligible wholesalers do not, to a significant extent, meet the industry standard level of sales of low volume medicines or sales to rural and remote pharmacy at the end of each year, eligibility will be reviewed and funding will be adjusted in the following year's monthly payments or recouped as required.
- 23.15. The cost of administering the CSO Funding Pool will be met from within the funding pool up to a maximum of \$1 million per annum.

## **PART 4-LOCATION RULES**

### **24. Preamble**

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- 24.1. The amendments to the Location Rules as set out in Attachment 1 are intended to provide greater flexibility to respond to community need for pharmacy services and to improve access to pharmacy services. These arrangements also aim to address those difficulties and anomalies in the Location Rules identified in the joint review of the Location Rules undertaken by the Commonwealth and the Guild in 2005.
- 24.2. The parties note that whilst changes to the Location Rules have been agreed, the current Location Rules will be extended to 30 June 2006 to allow the industry time to prepare for the changes. The parties agree to explore whether some anomalies in the current Location Rules can be addressed prior to 30 June 2006.

### **25. Objectives of Part 4**

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- 25.1. The objectives of the Location Rules are to ensure:
- a. all Australians have access to PBS medicines;
  - b. a commercially viable and sustainable network of community pharmacies dispensing PBS medicines;
  - c. improved efficiency through increased competition between pharmacies;
  - d. improved flexibility to respond to the community need for pharmacy services;
  - e. increased local access to community pharmacies for persons in rural and remote regions of Australia; and
  - f. continued development of an effective, efficient and well-distributed community pharmacy network in Australia.

### **26. Amendments to the Location Rules**

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- 26.1. Details of the amendments to the Location Rules which the parties have agreed are set out in Attachment 1.
- 26.2. The amendments to the Location Rules include relaxation of the Rules in the following three key areas:
- a. large medical centres;
  - b. smaller shopping centres with a large supermarket; and
  - c. large single pharmacy rural towns.

26.3. In addition, the Location Rules will be relaxed to give the ACPA discretion with respect to the method of determining the exclusion zone distance (ie straight line or shortest lawful access route) where there is genuine barrier to access to the proposed pharmacy in relation to the rules for medical centres, small shopping centres, single pharmacy towns and single pharmacy high growth urban areas.

26.4. The Commonwealth will put in place a process for the ACPA to refer anomalies in, and substantial problems arising from, the Rules to the Agreement Consultative Committee which will in turn advise the Minister on whether an amendment to the Rules is required.

**27. Timing of implementation of new Location Rules**

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27.1. It is the intention of the Commonwealth that there will be a new determination of the Minister under s.99L of the Act to take effect on 1 July 2006 and that this determination will reflect the changes to the Location Rules which the parties currently agree upon as set out in Attachment 1.

**28. Acknowledgement of parties of further review**

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28.1. The parties agree that prior to the expiry of the Agreement, they will undertake a review of the location rules in preparation for any subsequent Agreement.

## **PART 5-PROFESSIONAL PHARMACY PROGRAMS AND SERVICES**

### **29. What Part 5 does**

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- 29.1. Part 5 sets out the Programs which will be funded under the Agreement and the principles of accountability which will be adhered to in the spending and administration of the Funds.

### **30. Objective of Part 5**

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- 30.1. The objectives of Part 5 are to:
- a. recognise that beneficial health outcomes can be achieved through the delivery of evidence based professional pharmacy programs and services;
  - b. describe those professional pharmacy programs and services to be funded under this Agreement, which aim to optimise the effectiveness and value of the health system in general and the PBS in particular;
  - c. achieve a level of accountability and transparency in the administration and delivery of the Programs which ensure that the Programs are:
    - A. administered by the Department to the standards of accountability required of it under the FMA Act; and
    - B. delivered with the transparency which:
      - assures the community that the most efficient and effective health outcomes are being achieved for consumers; and
      - satisfies taxpayers that the Funds for the Programs are being properly expended in an efficient and accountable manner; and
  - d. clearly document the respective roles that the Guild and the Commonwealth will play in delivering and co-operating in Programs which will contribute to the long term health and well-being of the community.

### **31. Funding Arrangements**

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- 31.1. The Commonwealth and the Guild commit to ensuring that funding available under the Fourth Agreement is spent in a timely, accountable and transparent manner, with merit based assessment of proposals and, where appropriate, consultation with other relevant stakeholders.
- 31.2. The Department is required to ensure that funds available under the Professional Pharmacy Programs and Services are administered in a way that ensures that Government obtains best value for money in the administration and expenditure of the funds.
- 31.3. In recognition of the benefits to both parties, the Commonwealth and the Guild have agreed that \$500 million will be provided for Professional Pharmacy

Programs and Services over the life of the Fourth Agreement. This funding will be supplemented by the amount that remains unspent from the Pharmacy Development Program funding provided during the period of the Third Agreement, and as extended until the commencement of the Fourth Agreement. In addition, it will include an amount equal to 4 cents per PBS prescription dispensed during the period 1 July 2005 until the commencement of the Fourth Agreement inclusive.

- 31.4. The Third Community Pharmacy Agreement made provision of a total of \$400 million for pharmacy programs. This funding included an amount contributed by pharmacy, funded through a reduction in the Dispensing Fee from 1 July 2000 to the end of the Third Agreement. At the conclusion of the Third Agreement, the Dispensing Fee had been reduced by a total of 21 cents per prescription.
- 31.5. The parties recognise that pharmacists have made a financial contribution (as described in clause 31.4) to the funding of the pharmacy programs. Both parties agree to negotiate in good faith on how this contribution will be recognised in any new pharmacy remuneration arrangements.

## **32. Administrative Arrangements**

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- 32.1. The Professional Programs and Services Advisory Committee will provide advice to the Minister on the funding of projects and management responsibilities for projects and programs under the Professional Pharmacy Programs and Services. The Minister will make all reasonable endeavours to consider this advice within two months of its receipt from the Committee.
- 32.2. Organisations managing the programs will do so under an agreement with the Commonwealth which will require a standard of accountability and transparency which meets the requirements of the FMA Act.
- 32.3. The parties agree that there will be a transition period of six months from commencement of the Fourth Agreement to ensure that those programs under the Third Agreement that are agreed to continue under the Fourth Agreement can be transferred without interruption. This will also provide sufficient time for the new Agreement committee structure to be established.
- 32.4. The parties agree that, for the transition period of six months from commencement of the Fourth Agreement, arrangements will be made for the Guild to be provided with administration funding to enable the Guild to continue their existing role in supporting and/or managing those Third Agreement programs that continue into the Fourth Agreement. The amount of administration funding to be provided will be negotiated in relation to each program and deducted from the total funding available for each program.

### **33. Specific programs to be funded**

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33.1. The priorities for funding during the Agreement are:

- a. **Medication Management Review.** The aim of this Program is to enhance the Quality Use of Medicines and reduce the number of adverse drug events experienced by the elderly and others using multiple medicines by assisting them to better manage their medicines. Funding under this Program will be \$150 million.

Priorities agreed for this Program are:

- A. residential medication management review services
- B. home medicines review services
- C. accreditation incentives, and
- D. pharmacy services facilitators.

The Professional Programs and Services Advisory Committee may advise the Minister to fund additional programs that fall within the general objectives for this Program.

- b. **Rural Pharmacy Allowance and Support.** The aim of this Program is to maintain and improve access to quality community pharmacy services for the community in rural and remote areas of Australia and to increase the proportion of the total pharmacy workforce starting practice in rural and remote Australia and staying in rural and remote practice for at least five years. Funding under this Program will be \$111 million.

Priorities agreed for this program are:

- A. rural pharmacy maintenance allowance;
- B. new pharmacy start-up and support allowance;
- C. succession planning and incentives;
- D. rural pharmacist pre-registration incentive;
- E. rural pharmacy workforce program;

Specific performance targets will be set, taking into account the Rural Program Evaluation undertaken as part of the Third Agreement and input from the Professional Programs and Services Advisory Committee.

The Professional Programs and Services Advisory Committee may advise the Minister to fund additional programs that fall within the general objectives for this Program.

- c. **Indigenous Access.** This program aims to improve access to community pharmacy services by indigenous Australians by taking account of cultural issues in meeting Indigenous health needs.

Priorities agreed for this program:

- A. recognise cultural preferences of Aboriginal and Torres Strait Islander peoples in community pharmacy health care delivery;
- B. provide ongoing funding through the community pharmacy 'section 100' support allowances to improve access and quality use of medicines by clients of eligible remote area Aboriginal Health Services (AHSs);
- C. improve PBS accessibility for Aboriginal and Torres Strait Islander peoples through the community pharmacy network in rural and urban Australia;

and include:

- D. the Aboriginal and Torres Strait Islander (ATSI) Undergraduate Pharmacy Scholarship Scheme and the ASTI Pharmacy Assistant Scholarship Scheme.

Funding of \$27 million will be provided over the life of the Fourth Agreement to support these activities.

The Professional Programs and Services Advisory Committee may advise the Minister to fund additional programs that fall within the general objectives for this Program.

- d. **Better Community Health.** This is a new Program which will fund innovative projects in pharmacy as part of primary care and community health. Projects will be developed in partnerships between government, pharmacists and other health professionals. Funding of \$192 million, plus 100% of the supplementary funds described in clause 31.3, will be made available for this Program.

Priorities agreed for this program are:

- A. asthma pilot program – to build on the research undertaken during the Third Agreement by incorporating pharmacists' services into mainstream asthma care;
- B. diabetes pilot program – to build on the research undertaken during the Third Agreement by incorporating pharmacists' services into mainstream diabetes care;
- C. dose administration aids – to reduce medication-related hospitalisation and adverse events through improving medication compliance for

people in the community, including those on multiple medications or who are confused;

- D. prevention of communicable diseases – in keeping with national strategies on communicable diseases, education and awareness activities through community pharmacy;
  - E. improved counselling for dispensing of emergency contraception;
  - F. quality care pharmacy program – ongoing maintenance of the standard of customer service in individual pharmacies across Australia providing an industry wide guarantee of retail service quality and professional service;
  - G. patient medication profiling service – to reduce the risk of medication-related adverse events and to educate and involve people as to their medications by providing people with clear and concise summary of their current medications;
  - H. practice change and education incentive scheme – to incentivise and facilitate business, workflow, IT and/or human resource structural changes in community pharmacies, to enable the delivery of professional services in the Fourth Agreement;
  - I. research and development; and
  - J. other projects delivering improved health outcomes identified by the Professional Programs and Services Advisory Committee, in consultation with other stakeholders, and a merit based allocation of funds.
- e. **E-Health Initiatives.** The parties are committed to pursue e-health initiatives involving community pharmacies. Funding of \$20 million will be made available for these initiatives.

33.2. A summary of indicative funding allocations for all programs is set out in Attachment 2. While these indicative funding allocations reflect present priorities, the parties acknowledge that they may be reallocated during the period of the Fourth Agreement to reflect changing priorities.

## **PART 6-OTHER MATTERS**

### **34. PBS drugs to be available**

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- 34.1. The parties agree they will work together to ensure that manufacturers and wholesalers have stocks of drugs listed on the PBS available for timely supply to pharmacists to enable pharmacists to supply patients on demand. The parties agree that approved pharmacists will keep adequate medicine stocks for the supply of pharmaceutical benefits to ensure reasonable and timely access to those medicines by consumers.

### **35. Drug Recalls**

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- 35.1. The parties agree that a special working party will be convened by the Guild and the Department to undertake a review, within the first year of the Fourth Agreement, of the role of community pharmacies in drug recalls.

### **36. PBS Price Changes**

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- 36.1. The parties agree that price changes will not be announced more frequently than four monthly.
- 36.2. The parties also agree to jointly monitor the effect of PBS price changes on pharmacists and that the Agreement Consultative Committee will consider this issue further during the term of the Agreement.

### **37. Section 100 of the National Health Act**

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- 37.1. The parties agree to undertake a review of existing supply arrangements relating to drugs listed under Section 100 of the Act, including how these arrangements impact on community pharmacy, within the first year of the Agreement.

### **38. Aged Care Residential Facilities and Private Hospitals**

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- 38.1. The parties agree to undertake a review of the existing PBS supply arrangements in the context of aged care residential facilities and private hospitals, within the first year of the Agreement.

### **39. Recording of PBS Prescriptions priced below the Patient Co-Payment**

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- 39.1. The parties agree that, by the end of the Agreement, they will make all reasonable efforts to facilitate the online collection and recording of relevant data on PBS prescriptions supplied by community pharmacy that are priced below the patient co-payment. The parties also agree that the appropriate vehicle to achieve this objective is PBS Online.

- 39.2. To this end the parties agree that prior to 31 December 2006 they will jointly develop strategies and processes to facilitate the uptake of online collection and recording of under co-payment data.

#### **40. Other Issues for Review**

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- 40.1. The parties agree that during the first year of the Agreement they will review issues with potential impact on community pharmacy. Issues currently identified are:
- a. Payment times for processing by Medicare Australia of PBS claims; and
  - b. The staged supply of PBS medicines when this is specified by the prescriber.

#### **41. Arrangements at the end of the Agreement**

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- 41.1. The parties will make their best endeavours to ensure that negotiations for a new Agreement will commence 12 months prior to the expiry of the Agreement, and conclude by 31 March 2010.
- 41.2. If, at the end of the Agreement, Program funds remain unspent, such unspent funds will be taken into account for the purposes of the new Agreement, consistent with the Commonwealth's accountability obligations.
- 41.3. The parties agree to take into account the value of the remuneration arrangements and pharmacy programs that are in place at the end of this Agreement (refer also clause 31.5) as the framework for the negotiations for the new Agreement.

#### **42. Notices**

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- 42.1. A notice under this contract is only effective if it is in writing, and dealt with as follows:
- a. *if given by the Pharmacy Guild to the Commonwealth* – addressed to:  
First Assistant Secretary  
Medical and Pharmaceutical Services Division  
MDP 61  
GPO Box 9848  
CANBERRA ACT 2601  
or as otherwise notified by the Commonwealth; or
  - b. *if given by the Commonwealth to the Pharmacy Guild* –addressed to:  
Executive Director

The Pharmacy Guild of Australia  
PO Box 7036  
Canberra Mail Centre ACT 2610  
or as otherwise notified by the Guild.

- 42.2. A notice is to be:
- a. signed by the person giving the notice and delivered by hand; or
  - b. signed by the person giving the notice and sent by pre-paid post; or
  - c. transmitted electronically by the person giving the notice by electronic mail or facsimile transmission.
- 42.3. A notice is deemed to be effected:
- a. *if delivered by hand* – upon delivery to the relevant address;
  - b. *if sent by post* – upon delivery to the relevant address;
  - c. *if transmitted electronically* – upon actual receipt by the addressee.
- 42.4 A notice received after 5.00 pm, or on a day that is not a Business Day in the place of receipt, is deemed to be effected on the next Business Day.

SIGNED by the Honourable Tony  
Abbott Minister For Health and  
Ageing, on behalf of the  
Commonwealth of Australia:

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Signature

In the presence of:

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Signature

THE SEAL OF THE PHARMACY  
GUILD OF AUSTRALIA was  
hereunto affixed in pursuance of a  
resolution of its National Council  
and in the presence of:

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Signature

National President

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Signature

Executive Director

### ATTACHMENT 1 - Revised Location Rules

Provision Type		Requirements	Distance Criteria	Additional Comments
<b>New Approvals</b>	General	Catchment area contains: <ul style="list-style-type: none"> <li>• at least 3,000 people</li> <li>• at least 1 full-time (or equivalent) medical practitioner</li> </ul>	At least 1.5 km (straight line) from nearest pharmacy	
	Rural	Location classified as PhARIA 2-6	At least 10 km (SLAR) from nearest pharmacy	Approval cannot be relocated from town in which it is approved
<b>Relocations</b>	Minor	Relocations freely permitted within: <ul style="list-style-type: none"> <li>• small or large shopping centres</li> <li>• private hospitals</li> <li>• within rural single pharmacy locations</li> </ul>	At least 10 km (SLAR) from nearest pharmacy for rural single pharmacy locations	
	Short		Not more than 1 km (straight line) from existing site <b>or</b> between 1 and 1.5 km (straight line) from existing site and at least 500 m (straight line) from nearest pharmacy (which is more than 1 km from existing site)	
	Long		At least 1.5 km (straight line) <b>or</b> 2 km (SLAR) from nearest pharmacy	

Provision Type		Requirements	Distance Criteria	Additional Comments
<b>Relocations (cont'd)</b>	Rural – additional pharmacy	Location classified as PhARIA 2-6 and catchment area contains: <ul style="list-style-type: none"> <li>• one pharmacy</li> <li>• at least 8,000 people</li> <li>• at least 4 full-time (or equivalent) medical practitioners</li> <li>• no amalgamation involving existing pharmacy in the three years preceding the application for relocation (providing the amalgamation occurred prior to 1 July 2006)</li> </ul>	At least 200 m, straight line (or SLAR in exceptional circumstances where there is a genuine barrier), from nearest pharmacy	
	Urban – additional pharmacy	Location classified as PhARIA 1 and catchment area contains: <ul style="list-style-type: none"> <li>• one pharmacy</li> <li>• at least 8,000 people</li> <li>• population has grown at least 5% over each of the past 2 years</li> </ul>	At least 500 m, straight line (or SLAR in exceptional circumstances where there is a genuine barrier), from nearest pharmacy	
<b>Special Relocations</b>	Small shopping centres	Shopping centre is under single management and contains: <ul style="list-style-type: none"> <li>• at least 5,000 m<sup>2</sup> of gross leasable area</li> <li>• at least 15 commercial establishments</li> <li>• a supermarket of at least 2,500 m<sup>2</sup></li> <li>• car parking facilities</li> </ul>	At least 500 m, straight line (or SLAR in exceptional circumstances where there is a genuine barrier), from nearest pharmacy	<ul style="list-style-type: none"> <li>• Pharmacy cannot subsequently relocate from centre using short relocation</li> <li>• Pharmacy is disregarded in respect of the relocation of other pharmacies using distance criteria</li> </ul>
	Large shopping centres	Shopping centre is under single management and contains: <ul style="list-style-type: none"> <li>• at least 5,000 m<sup>2</sup> of gross leasable area</li> <li>• at least 30 commercial establishments</li> <li>• a supermarket of at least 1,000 m<sup>2</sup></li> <li>• car parking facilities</li> <li>• (100 commercial establishments for 2<sup>nd</sup> pharmacy; 200 for 3<sup>rd</sup>)</li> </ul>	N/A	<ul style="list-style-type: none"> <li>• Pharmacy cannot subsequently relocate from centre using short relocation</li> <li>• Pharmacy is disregarded in respect of the relocation of other pharmacies using distance criteria</li> </ul>

Provision Type		Requirements	Distance Criteria	Additional Comments
<b>Special Relocations (cont'd)</b>	Private hospitals	Private hospital: <ul style="list-style-type: none"> <li>contains no pharmacy (s.90 or s.94)</li> <li>is licensed/registered to treat 150 patients or contain 150 beds</li> </ul>	N/A	<ul style="list-style-type: none"> <li>May establish ancillary satellite dispensaries within hospital which serve in-patients only</li> <li>Pharmacy cannot subsequently relocate from hospital using short relocation</li> <li>Pharmacy is disregarded in respect of the relocation of other pharmacies using distance criteria</li> </ul>
	Medical centres	Medical centre is under single management, operates for at least 55 hours per week and contains (and has for the last six months) at least eight full-time (or equivalent) general practitioners.  Any pharmacy approved to locate within a medical centre will be required to demonstrate that, it has made or will make, all reasonable attempts to ensure that the pharmacy's hours of operation will satisfy the needs of the patients attending the medical centre for timely access to pharmacy services	At least 500 m, straight line (or SLAR in exceptional circumstances where there is a genuine barrier), from nearest pharmacy  500m exclusion zone	<ul style="list-style-type: none"> <li>Pharmacy cannot subsequently relocate from centre using short relocation</li> <li>Pharmacy is disregarded in respect of the relocation of other pharmacies using distance criteria</li> <li>Any pharmacy, or a combination of pharmacies, located within the exclusion zone will be required to demonstrate that all reasonable attempts have been made to ensure that the pharmacy/s hours of operation satisfy the needs of the patients attending the medical centre for timely access to pharmacy services</li> </ul>
	Supermarkets	Pharmacy cannot be approved where it is publicly accessible from within a supermarket		New definition for supermarket will address potential anomalies

Provision Type		Requirements	Distance Criteria	Additional Comments
General	Two year requirement	<p>Pharmacy must be approved at its existing site for at least two years before it can be relocated, except where relocation is:</p> <ul style="list-style-type: none"> <li>• within a large shopping centre</li> <li>• within a private hospital</li> <li>• within a rural single pharmacy location</li> <li>• into temporary premises resulting from renovation or refurbishment</li> <li>• returning to substantially the same premises following renovation or refurbishment</li> <li>• result of exceptional circumstances</li> </ul>		If a pharmacy in a large shopping centre, private hospital or within a rural single pharmacy town subsequently relocates from the centre or hospital or rural location, it is taken to have been operating continuously from the time the original premises were approved
	Admin.	Non-trading pharmacies	If a non-trading pharmacy has been recommended to be relocated, its existing site will not be treated as an approved pharmacy	
	Extensions of time	ACPA may only grant two extensions of time to an application which has been recommended for approval		
	Expansions / contractions	Are not treated as relocations		

Provision Type		Requirements	Distance Criteria	Additional Comments
Admin (cont'd)	Discretion	Where unique circumstances arise which are not expressly provided for in the Rules, the Minister can substitute a decision of the Secretary where that decision, when applying the rules, results in an unmet community need for pharmacy services. Ministerial discretion will only be exercised following completion of due legislative process (ie ACPA recommendation, finalisation of legal appeals if applicable and Secretary's decision to approve or not approve the application)		
	ACPA membership	Will include consumer representation		

**ATTACHMENT 2 - Summary of Indicative Funding Allocations for Fourth Agreement  
Professional Pharmacy Programs & Services**

	<b>Total Cost \$m</b>	<b>Supplementary Funding<sup>16</sup> \$m</b>
<b>Better Community Health</b>		
Quality Care Pharmacy Program	73.5	2.3
Dose Administration Aids	39.7	33.2
Patient Medication Profiling Service	14.8	18.8
Practice Change and Education Incentive Scheme	9.3	1
Diabetes Pilot Program	10.4	2.5
Asthma Pilot Program	10.4	2.5
Improved Counselling for Dispensing of Emergency Contraception	10.5	1.5
Prevention of Communicable Diseases	9.4	0.9
Research and Development	14.0	5.3
<b>eHealth</b>	<b>20.0</b>	<b>0</b>
<b>Medication Reviews</b>		
Residential Medication Management Reviews	66.75	0
Home Medicine Reviews	54.15	0
Medication Management Reviews Facilitators	29	0
Accreditation Incentives	0.4	0
<b>Rural Programs</b>		
Workforce Program	25.3	0
Pre-Registration Allowance	10.4	0
Rural Pharmacy Maintenance Allowance/Start up & Succession Allowances	75.0	0
<b>Aboriginal and Torres Strait Islander Programs</b>		
Improved Access to PBS	10.0	0
Section 100 Support allowances	13.4	0
Aboriginal and Torres Strait Islander Undergraduate Pharmacy Scholarship Scheme	3.0	0
Aboriginal and Torres Strait Islander Pharmacy Assistant Scholarship Scheme	0.6	0
<b>TOTAL</b>	<b>500.0</b>	<b>68.0</b>

<sup>16</sup> This represents the amount that remains unspent from the Pharmacy Development Program funding provided during the period of the Third Agreement, and as extended until the commencement of the Fourth Agreement. In addition, it will include an amount equal to 4 cents per PBS prescription dispensed during the period 1 July 2005 until the commencement of the Fourth Agreement inclusive (refer clause 31.3).

## **ATTACHMENT 3 – The Schedule – Draft PBRT Determination**

COMMONWEALTH OF AUSTRALIA

*National Health Act 1953*

PHARMACEUTICAL BENEFITS

### **DETERMINATION UNDER PARAGRAPH 98B (1) (a)**

#### **Part I — General**

1. Pursuant to paragraph 98B(1)(a) of the *National Health Act 1953*, the Pharmaceutical Benefits Remuneration Tribunal hereby determines that the manner in which the Commonwealth price of all or any pharmaceutical benefits is to be worked out for the purpose of payments to approved pharmacists in respect of the supply by them of pharmaceutical benefits is as set out in this determination. This determination is made in accordance with clauses 12-16 of the Agreement made on 16 November 2005 between the Minister for Health and Ageing (acting on the Commonwealth's behalf) and The Pharmacy Guild of Australia for the purpose of section 98BAA of the *National Health Act 1953*.
2. This determination will come into operation on 1 December 2005 and will remain in force until such time as a further determination is made by the Pharmaceutical Benefits Remuneration Tribunal.
3. The determination under paragraph 98B(1)(a) of the Act made on 16 June 2005 with effect from 1 July 2005 is repealed with effect from 1 December 2005.
4. This determination includes the appendices hereto and consists of the following Parts:
  - Part I — General
  - Part II — Ready-Prepared Pharmaceutical Benefits
  - Part III — Extemporaneously-Prepared Pharmaceutical Benefits
5. This determination will not apply to the supply of a pharmaceutical benefit by an approved pharmacist to a medical practitioner for the purpose of section 93 of the Act.
6. In this determination:
  - “approved price to pharmacists” has the same meaning as in subsection 98B(3) of the Act;
  - “basic wholesale price” has the same meaning as in subsection 98B(3) of the Act;
  - “dangerous drug fee” means an amount \$2.61;
  - “exceptional prescription” means a prescription for an extemporaneously-prepared pharmaceutical benefit which is not a standard formula preparation and for which the price of the ingredients, calculated in accordance with paragraphs 22 to 25, is not less than twice the amount calculated in accordance with paragraph 37, excluding container price and dispensing fee;

“extemporaneously-prepared dispensing fee” means an amount of \$6.97;

“extemporaneously-prepared pharmaceutical benefit” means a pharmaceutical benefit other than a ready-prepared pharmaceutical benefit;

“ready-prepared dispensing fee” means \$4.94;

“ready-prepared pharmaceutical benefit” means a pharmaceutical benefit in respect of which there is in force a determination under subsection 85 (6) of the Act;

“standard formula preparation” means an extemporaneously-prepared pharmaceutical benefit that is specified in Schedule 5 to the determination in force under paragraph 98C (1) (b) of the Act;

“the Act” means the *National Health Act 1953*;

“the Minister” means the Minister for Health and Ageing;

“the Regulations” means the *National Health (Pharmaceutical Benefits) Regulations 1960* made under the Act.

7. In addition to the amount calculated in accordance with Part II of this determination the Commonwealth price will include a dangerous drug fee in respect of those ready-prepared pharmaceutical benefits specified in Schedule 3 to the determination in force under paragraph 98C (1) (b) of the Act to be dangerous drugs for the purpose of payment of a dangerous drug fee and in respect of those ready-prepared pharmaceutical benefits prescribed by State or Territory legislation to be treated similarly to dangerous drugs.
8. In addition to the amount calculated in accordance with Part II or Part III of this determination, as the case may be, the Commonwealth price for a pharmaceutical benefit supplied by an approved pharmacist at or from premises located in Western Australia will include an allowance for freight costs ascertained in accordance with the following table:

<i>Location of premises in respect of which the pharmacist is approved</i>	<i>Freight allowance</i>
Places within the metropolitan area of Perth as defined in the <i>Electoral Districts Act 1947</i> of Western Australia	Nil
Other places not more than 100 kilometres from the General Post Office, Perth	\$0.06
Places more than 100 kilometres but not more than 400 kilometres from the General Post Office, Perth	\$0.11
Places more than 400 kilometres but not more than 1,000 kilometres from the General Post Office, Perth	\$0.13
Places more than 1,000 kilometres from the General Post Office, Perth	\$0.29

9. For the purposes of this determination, the manufacturers' packs of pharmaceutical benefits on which the approved prices to pharmacists are based are:
  - (a) standard packs — a standard pack for a ready-prepared benefit is the pack that contains a quantity or number of units of the benefit equal to the quantity or number of units specified as the maximum quantity of the benefit in the determination in force under paragraph 85A (2) (a) of the Act; and
  - (b) non-standard packs — a non-standard pack for a ready-prepared benefit is any pack of the benefit, other than a standard pack, that is used for pricing purposes; and
  - (c) for drugs used in extemporaneously-prepared benefits, the agreed purchase quantity is that agreed upon between the Minister and The Pharmacy Guild of Australia.
10. Where, in accordance with subsection 88 (6) of the Act and regulation 24 of the Regulations, a medical practitioner, instead of directing a repeated supply of a pharmaceutical benefit, directs the supply on one occasion of a quantity or number of units of the benefit, not exceeding the total quantity or number of units that could be prescribed if the medical practitioner directed a repeated supply, the Commonwealth price for that supply will include only one dispensing fee and the appropriate price, if any, for the container.
11. A payment in respect of the supply of a pharmaceutical benefit will not be made unless supply of that pharmaceutical benefit was made in accordance with the Act, the Regulations and the relevant determinations made under the Act.
12. Where in respect of a drug or medicinal preparation there is a determination in force under subsection 85 (6) of the Act of a brand or brands under which that drug or medicinal preparation may be supplied as a pharmaceutical benefit under Part VII of the Act, no payment by the Commonwealth will be made in respect of the supply by an approved pharmacist of any other brand or brands of that drug or medicinal preparation.

## **Part II — Ready-Prepared Pharmaceutical Benefits**

13. The Commonwealth price for the supply of a ready-prepared pharmaceutical benefit will be —
  - (a) where a quantity of a benefit is ordered and supplied that is equal to the quantity contained in a standard or non-standard pack, the sum of:
    - (i) the approved price to pharmacists of that standard or non-standard pack, as applicable, plus mark-up as specified in paragraph 14, taken to the nearest cent, one half cent being counted as one cent; and
    - (ii) a ready-prepared dispensing fee, except in the case of a benefit that involves the admixture of ready-prepared ingredients and is specified in Schedule 1 to the determination in force under paragraph 98C (1) (b) of the Act, in which case an extemporaneously-prepared dispensing fee will apply;
  - (b) where a quantity of a benefit is ordered and supplied that is less than the quantity contained in a standard or non-standard pack, the sum of:
    - (i) the amount worked out in accordance with paragraph 17; and

- (ii) a ready-prepared dispensing fee for each supply of benefits made; and
  - (iii) an amount for the supply of a container, worked out in accordance with paragraph 15; or
- (c) where a quantity of a benefit is ordered and supplied which is more than the quantity contained in a standard or non-standard pack, the sum of:
- (i) the approved price to pharmacists, plus mark-up as specified in paragraph 14, taken to the nearest cent, one half cent being counted as one cent, for each complete standard or non-standard pack, as applicable, contained in the quantity supplied; and
  - (ii) the amount worked out in accordance with paragraph 17 in respect of that remainder, if any, of the quantity supplied that is less than the quantity contained in a standard or non-standard pack, as applicable; and
  - (iii) a ready-prepared dispensing fee, except in the case of a benefit that involves the admixture of ready-prepared ingredients and is specified in Schedule 1 to the determination in force under paragraph 98C (1) (b) of the Act, in which case an extemporaneously-prepared dispensing fee will apply (an additional amount for a container is not payable);
14. The mark-up referred to in this Part will be —
- (a) 10 per cent, where the approved price to pharmacists for the quantity or number of units of the benefit specified as the maximum quantity in the determination in force under paragraph 85A (2) (a) of the Act for that benefit is not more than \$180.00; or
  - (b) \$18.00, where the approved price to pharmacists for the quantity or number of units of the benefit specified as the maximum quantity in the determination in force under paragraph 85A (2) (a) of the Act for that benefit is more than \$180.00 but not more than \$450.00; or
  - (c) 4 per cent, where the approved price to pharmacists for the quantity or number of units of the benefit specified as the maximum quantity in the determination in force under paragraph 85A (2) (a) of the Act for that benefit is more than \$450.00.
15. The price for a container for a ready-prepared pharmaceutical benefit will be based on the average of wholesale costs for a particular container, supplied in a quantity of 100, obtained from wholesale drug distributors as agreed between the Minister and The Pharmacy Guild of Australia, increased by a mark-up of 10 per cent. The particular containers will be a 150 millilitres vial for use for injectables and a 25 millilitres vial for use for other ready-prepared pharmaceutical benefits. For this purpose the wholesale costs of containers will be ascertained as at 1 May in each year and will take effect on 1 August in the same year.
16. The price for a benefit or container will in each case be taken to the nearest cent, one half cent being counted as one cent.
17. Where a quantity of a benefit is ordered and supplied which is less than the quantity contained in a standard or non-standard pack (that is, a broken quantity), the amount referred to in subsubparagraph 13 (b) (i) or 13 (c) (ii) will be worked out by:

- (a) adding mark-up as specified in paragraph 14 to the approved price to pharmacists of the standard or non-standard pack, as applicable, and taking the result to the nearest cent, one half cent being counted as one cent;
- (b) ascertaining the percentage that the quantity or number of units in the broken quantity bears to the quantity or number of units in the standard or non-standard pack, as applicable;
- (c) selecting, in column A of the table set out hereunder, the percentage worked out in accordance with subparagraph (b), or, where that percentage is not specified in that column, the next higher percentage so specified;
- (d) taking the percentage set out in column B of the table set out hereunder, immediately below the percentage selected in accordance with subparagraph (b); and
- (e) taking that percentage, ascertained in accordance with subparagraph (d), of the amount worked out in accordance with subparagraph (a).

Column A — 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95 100 per cent

Column B — 10 18 26 32 38 44 50 54 58 62 66 70 74 78 82 86 90 94 98 100 per cent

- 18. Notwithstanding anything contained elsewhere in this determination, the Commonwealth price in respect of the supply of a quantity of a ready-prepared pharmaceutical benefit will not exceed the Commonwealth price for a greater quantity of that benefit.
- 19. Where a prescription calls for a quantity of one of the pharmaceutical benefits specified in Schedule 4 to the determination in force under paragraph 98C (1) (b) of the Act as being a benefit the complete pack of which will be supplied regardless of any lesser quantity ordered, the Commonwealth price will be worked out on the basis that the complete pack was supplied.

**Part III — Extemporaneously-Prepared Pharmaceutical Benefits**

20. In this Part:

“wastage” means the combined loss that arises from:

- (a) transferring drugs and chemicals from the package in which they are delivered to the approved pharmacist to the dispensing package delivered to the patient; and
- (b) deterioration; and
- (c) obsolescence.

21. The Commonwealth price of an extemporaneously-prepared pharmaceutical benefit, including a standard formula preparation, will, subject to paragraph 37, be the sum of the following amounts:

- (a) the amount in respect of the quantity supplied of each of the ingredients, worked out in accordance with paragraphs 22 to 25; and

- (b) the amount in respect of the appropriate container, worked out in accordance with paragraph 31; and
  - (c) an extemporaneously-prepared dispensing fee.
22. For the purposes of paragraph 21 the amount in respect of an ingredient of an extemporaneously-prepared pharmaceutical benefit, where the quantity of the ingredient is equal to the agreed purchase quantity, will be the sum of:
- (a) the basic wholesale price of the ingredient;
  - (b) mark-up, as specified in paragraph 23, on (a); and
  - (c) an amount where applicable representing mark-up on (a) to cover wastage, ascertained in accordance with Appendix A.
23. The mark-up referred to in this Part will be —
- (a) 10 per cent, where the basic wholesale price for the agreed purchase quantity of the ingredient is not more than \$180.00; or
  - (b) \$18.00, where the basic wholesale price for the agreed purchase quantity of the ingredient is more than \$180.00 but not more than \$450.00; or
  - (c) 4 per cent, where the basic wholesale price for the agreed purchase quantity of the ingredient is more than \$450.00.
24. For the purposes of paragraph 21 the amount in respect of an ingredient of an extemporaneously-prepared pharmaceutical benefit, where the quantity of the ingredient is less than the agreed purchase quantity, will be ascertained as follows:
- (a) by ascertaining the basic pricing unit to be used for the quantity to be dispensed by reference to the table of basic pricing units in Appendix B;
  - (b) by ascertaining the cost of the basic pricing unit by reducing the amount ascertained in accordance with paragraph 21 by the quantity factor or factors shown in Appendix B appropriate to the basic pricing unit required and rounding off the resultant amount to the nearest cent, one half cent being counted as one cent; and
  - (c) by multiplying the cost of the basic pricing unit by the fraction that the quantity to be dispensed bears to the quantity contained in the basic pricing unit, except for:
    - (i) quantities exceeding 700 milligrams or 700 microlitres but not exceeding 1 gram or 1 millilitre, which will be priced at the amount for 1 gram or 1 millilitre;
    - (ii) quantities exceeding 7 grams or 7 millilitres but not exceeding 10 grams or 10 millilitres, which will be priced at the amount for 10 grams or 10 millilitres; and
    - (iii) quantities exceeding 80 grams or 80 millilitres but not exceeding 90 grams or 90 millilitres, which will be priced at the amount for 80 grams or 80 millilitres.

For the purposes of this paragraph the quantity of the ingredient will be calculated to the next higher 50 milligrams or 50 microlitres.

25. For the purposes of paragraph 21 the amount in respect of an ingredient of an extemporaneously-prepared pharmaceutical benefit, where the quantity of the ingredient is greater than the agreed purchase quantity, will be worked out as follows:
- (a) except in the case of drugs which are unstable or packed sterile, as specified in Schedule 2 to the determination under paragraph 98C (1) (b) of the Act, by dividing the quantity dispensed by the quantity contained in the agreed purchase quantity and multiplying by the basic wholesale price of the agreed purchase quantity; or
  - (b) where the ingredient is one of the drugs which are unstable or packed sterile, as specified in Schedule 2 to the determination under paragraph 98C (1) (b) of the Act, by multiplying the price of the agreed purchase quantity by the number of whole packs of the agreed purchase quantity required to dispense the quantity of the ingredient.
26. The Commonwealth price in respect of an extemporaneously-prepared pharmaceutical benefit which comprises a vehicle which is specified in the prescription under a particular name and an additional specified ingredient or ingredients will be calculated in accordance with the provisions of paragraph 27 or 28 as applicable.
27. Where the vehicle is a single liquid ingredient and one or more other ingredients are added, displacement of the vehicle by solids (if any) will be disregarded for pricing purposes and the Commonwealth price for the pharmaceutical benefit as a whole will be calculated in accordance with the provisions of paragraph 21.
28. Where the vehicle is compounded from two or more ingredients and one or more other ingredients are added, displacement of the vehicle by solids (if any) will be disregarded for pricing purposes and the amounts for the respective ingredients will be the sum of:
- (a) the price of each ingredient of the vehicle; and
  - (b) the price of each ingredient that is added to the vehicle;
- worked out in each case in accordance with paragraph 22, 24 or 25 as applicable.
29. The basic wholesale price of a drug used in the preparation of an extemporaneously-prepared pharmaceutical benefit will be calculated as the arithmetic average of wholesale costs of the drug, in a purchase quantity agreed upon by the Minister and The Pharmacy Guild of Australia and available from wholesale drug distributors. For this purpose the basic wholesale price of a drug will be ascertained as at 1 May in each year and will take effect on 1 August in the same year.
30. In calculating the amount in respect of an ingredient or the basic wholesale price of a basic pricing unit, the amount so calculated will be taken to the nearest cent, one half cent being counted as one cent, provided that the minimum amount in respect of an ingredient will be one cent.
31. The price for each size and type of container for extemporaneously-prepared pharmaceutical benefits will be based on the average of wholesale costs for that container, in the purchase quantity agreed upon between the Minister and The Pharmacy Guild of Australia and available from wholesale drug distributors, increased by a mark-up of 10 per cent, taken to the nearest cent, one half cent being counted as one cent. For

this purpose the wholesale costs of the particular containers will be ascertained as at 1 May in each year and will take effect on 1 August in the same year.

32. Where a wholesale drug distributor will not supply containers of a particular size or type in the purchase quantity agreed upon by the Minister and The Pharmacy Guild of Australia, the price of the purchase quantity will be calculated by multiplying the price of the smallest quantity above the agreed purchase quantity, in which the distributor will supply containers of that size and type, by the fraction that the quantity in the agreed purchase quantity bears to the quantity in which the distributor will supply.
33. In the case of bulk powders the price for the container will be the price for a screw cap jar which is nominally rated to hold at least double the quantity supplied.
34. Where a prescription orders a quantity of an extemporaneously-prepared pharmaceutical benefit in excess of the capacity of the largest size container of the appropriate type for which provision is made, the price for the container will be calculated as if the pharmaceutical benefit had been supplied in more than one of the containers for which provision is made.
35. Notwithstanding anything contained elsewhere in this determination, the Commonwealth price in respect of the supply of a quantity of an extemporaneously-prepared pharmaceutical benefit will not exceed the Commonwealth price for a greater quantity of that benefit.
36. Notwithstanding anything contained elsewhere in this determination, in calculating the price in respect of the supply of a quantity of an ingredient of an extemporaneously-prepared pharmaceutical benefit, that price will not exceed the price of a greater quantity of that ingredient.
37. Extemporaneously-prepared pharmaceutical benefits that are not standard formula preparations will be classified for pricing purposes according to the form of preparation in accordance with the Fourth Schedule to the determinations in force under sections 85, 85A and 88 of the Act. Except in the case of exceptional prescriptions or where the approved pharmacist has made an election pursuant to paragraph 38, the Commonwealth price for such a pharmaceutical benefit will be worked out as follows:
  - (a) on the sixteenth day of the month or as near as practicable thereto the total number of grams or millilitres, as the case may be, priced during the previous four weeks or period as near as practicable thereto, for each form of preparation will be ascertained together with the total amount (exclusive of container costs and dispensing fee) paid for each total quantity;
  - (b) the total amount paid (exclusive of container costs and dispensing fee) ascertained in accordance with subparagraph (a) for each type of preparation will be divided by a number equal to one-tenth of the number of grams or millilitres, as the case may be, for that form of preparation, ascertained in accordance with subparagraph (a);
  - (c) the Commonwealth price will be the average 10 grams or 10 millilitres rate ascertained in accordance with subparagraph (b) calculated at about the sixteenth day of the month prior to the month of supply for the particular form of preparation, multiplied by one-tenth of the number of grams or millilitres, plus an

extemporaneously-prepared dispensing fee and an amount for a container worked out in accordance with paragraph 31;

- (d) on the sixteenth day of the month or as near as practicable thereto, if no prescriptions have been priced during the previous four weeks or period as near as practicable thereto for any of the standard formula preparations listed for a particular form of preparation, the Commonwealth price will be ascertained by taking the average 10 grams or 10 millilitres rate (exclusive of container costs and dispensing fee) of all the standard formula preparations determined for that form of preparation multiplied by one-tenth of the number of grams or millilitres, plus an extemporaneously-prepared dispensing fee and an amount for a container worked out in accordance with paragraph 31;
- (e) the Commonwealth price of a benefit worked out in accordance with subparagraph (c) or (d) will in either case be taken to the nearest cent, one half cent being counted as one cent.

- 38. An approved pharmacist may elect to calculate Commonwealth prices of extemporaneously-prepared pharmaceutical benefits that are not standard formula preparations in accordance with paragraph 21 instead of receiving payment in accordance with paragraph 37.
- 39. Where an approved pharmacist who has not made an election pursuant to paragraph 38 supplies an extemporaneously-prepared pharmaceutical benefit and there is no standard formula preparation of the form supplied (and an average price is therefore not available), the Commonwealth price of the benefit will be worked out in accordance with paragraph 21.
- 40. Where the benefit comprises a standard formula preparation plus an additive, and the approved pharmacist has not made an election pursuant to paragraph 38, the amount payable will be the Commonwealth price worked out in accordance with paragraph 37, unless the approved pharmacist indicates that the benefit is to be priced as if the prescription had specified only the standard formula preparation without the additive, in which case the amount payable will be the Commonwealth price for the standard formula preparation without the additive worked out in accordance with paragraph 21.
- 41. Notwithstanding the provisions of paragraph 37, an approved pharmacist who has not made an election pursuant to paragraph 38 may calculate the Commonwealth price for an exceptional prescription in accordance with paragraph 21.

Dated this the        day of November 2005.

J. Hamberger  
Chairperson

H. Lapsley  
Member

B. Frost  
Member

APPENDIX A — CLASSIFICATION AND MARK-UP TABLES

*Table 1 – Basic wholesale price for the agreed purchase quantity not more than \$180.00*

A. Classification No.	1.	2.	3.	4.	5.
B. Basic Wholesale Price	100	100	100	100	100
C. 10 per cent mark-up on B.	10	10	10	10	10
D. Wastage Factor on B.	0	10	20	30	40
E. Total of B., C. and D.	110	120	130	140	150
F. Per cent mark-up on B.	10	20	30	40	50

*Table 2 – Basic wholesale price for the agreed purchase quantity more than \$180.00 but not more than \$450.00*

A. Classification No.	1.	2.	3.	4.	5.
B. Basic Wholesale Price	100	100	100	100	100
C. Mark-up on B.	\$18	\$18	\$18	\$18	\$18
D. Wastage Factor on B.	0	10	20	30	40
E. Total of B., C. and D.	100 +\$18	110 +\$18	120 +\$18	130 +\$18	140 +\$18

*Table 3 – Basic wholesale price for the agreed purchase quantity more than \$450.00*

A. Classification No.	1.	2.	3.	4.	5.
B. Basic Wholesale Price	100	100	100	100	100
C. 4 per cent mark-up on B.	4	4	4	4	4
D. Wastage Factor on B.	0	10	20	30	40
E. Total of B., C. and D.	104	114	124	134	144
F. Per cent mark-up on B.	4	14	24	34	44

## APPENDIX B — BASIC PRICING UNITS

<i>Quantity</i>	<i>Basic Pricing Unit to be Used</i>
Up to and including 700 milligrams or 700 microlitres	100 milligrams or 100 microlitres price
Over 700 milligrams or 700 microlitres and up to and including 1 gram or 1 millilitre	price as 1 gram or 1 millilitre
Over 1 gram or 1 millilitre and up to and including 7 grams or 7 millilitres	1 gram or 1 millilitre price
Over 7 grams or 7 millilitres and up to and including 10 grams or 10 millilitres	price as 10 grams or 10 millilitres
Over 10 grams or 10 millilitres and up to and including 80 grams or 80 millilitres	10 grams or 10 millilitres price
Over 80 grams or 80 millilitres and up to and including 90 grams or 90 millilitres	price as 80 grams or 80 millilitres
Over 90 grams or 90 millilitres	100 grams or 100 millilitres price

### *Quantity Factors*

To ascertain the 100 grams or 100 millilitres price, divide the 500 grams or 500 millilitres price by 5 or divide the 1 kilogram or 1 litre price by 10.

To ascertain the 10 grams or 10 millilitres price, divide the 100 grams or 100 millilitres price plus 12½ per cent by 10.

To ascertain the 1 gram or 1 millilitre price, divide the 10 grams or 10 millilitres price plus 25 per cent by 10.

To ascertain the 100 milligrams or 100 microlitres price, divide the 1 gram or 1 millilitre price plus 25 per cent by 10.

## ***Introduction***

This paper provides further detail for pharmacists about the PBS reform measures and associated implementation timeframe in addition to that released by the Minister for Health and Ageing on 16 November 2006.

Some of the measures require changes to the *National Health Act 1953* and associated instruments. Information is provided here subject to passage of relevant amendments through Parliament.

## ***2. Background***

The Government is making changes to the Pharmaceutical Benefits Scheme (PBS) to give Australians continued access to new and expensive medicines while ensuring the PBS remains affordable into the future.

The reforms comprise a range of inter-connected measures:

- Changes to the pricing of PBS listed medicines;
- Pharmacy and pharmaceutical wholesaler compensation arrangements;
- Streamlined authority approvals for some medicines; and
- Establishment of an access to medicines working group.

The Government is also considering a generic medicines awareness campaign.

It is timely to introduce these changes, with the PBS entering a phase of lower, more stable growth and with the knowledge that patents for over 100 drugs will be expiring in the next ten years. These changes will make the PBS an even stronger system with the government paying less for certain medicines without increasing the cost to patients.

## ***3. Measures***

### ***3.1. Changes to the Pricing of PBS listed medicines***

#### ***3.1.1 Creation of formularies***

From 1 August 2007, PBS medicines will be listed on two separate formularies:

- Formulary 1 (F1) will comprise single brand medicines. However, it will not contain single brand medicines which are interchangeable at the patient level<sup>17</sup> with multiple brand medicines<sup>18</sup>; and

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<sup>17</sup> Medicines in the following groups have been recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) and determined by the Minister to be interchangeable at the patient level: ACE inhibitors, angiotensin II receptor antagonists, calcium channel blockers, H2 receptor antagonists, proton pump inhibitors and the HMG Coenzyme A reductase inhibitors (pravastatin & simvastatin only).

<sup>18</sup> Medicines will move from F1 to F2A from time to time, as new brands of F1 medicines are listed on the PBS and competition for the supply of those medicines commences.

- Formulary 2 (F2) will comprise multiple brand medicines and any single brand medicines which are interchangeable with multiple brand medicines at the patient level.

A medicine will be classified into only one formulary. If one formulation or strength of a medicine has multiple brands, then the entire molecule will be listed on the F2 formulary, even if multiple brands are not available in other formulations or strengths of that medicine. Formulary lists as at 1 December 2006 were distributed to stakeholders on 20 December 2006. A final list will be determined by 31 March 2007 for implementation from 1 August 2007.

Over the counter medicines subsidised through the PBS will be separately flagged and distributed across the formularies subject to the same pricing arrangements as apply within each formulary.

### **3.1.2 Ongoing price links**

- There will be no ongoing price links across medicines listed on F1 and those listed on F2. Attachment A provides examples of how current reference pricing groups will apply when the formularies take effect.
- Reference pricing will continue to apply between medicines that are linked within reference pricing groups on F1.
- Reference pricing will continue to apply within Therapeutic Group Premium (TGP) groups and across different brands of the same medicine listed on F2.

### **3.1.3 Pricing mechanisms**

#### **3.1.3.1 Price disclosure**

Over time, medicines listed on F2 will move to a system of price disclosure where the price that the Government pays will reflect more closely the actual price at which the medicine is being supplied to wholesalers and pharmacists.

A transitional pricing arrangement will apply to F2 with two sub-formularies being created:

- Formulary 2A (F2A) will comprise medicines that did not attract significant trading terms to pharmacy at 1 October 2006 (i.e. less than 25%).
- Formulary 2T (F2T) will comprise medicines that did attract significant trading terms to pharmacy at 1 October 2006 (i.e. 25% or more), and other medicines interchangeable with them at the patient level.

#### **3.1.3.2 All medicines on F2A**

Medicines on F2A will be subject to the following pricing arrangements:

- Staged price reductions of 2% per year for three years will apply commencing on 1 August 2008.
- The 12.5% price reduction policy will continue to apply, where relevant.
- Price reductions for medicines on F2A will apply to all brands, forms and strengths of that medicine and to products that are interchangeable with that medicine.
- Price disclosure:
  - Suppliers listing a new brand on or after 1 August 2007 must agree to disclose the actual market price as a condition of listing. Staged price reductions for that medicine will apply until such time as the price of the medicine is based on the disclosed price.

- The first price reductions resulting from disclosure will take effect from 1 August 2009. Price reductions will reflect the weighted average disclosed price, taking account of volume and price information for each disclosing supplier.
- The first disclosure of pricing information for an item will include at least 12 months of data. Pricing based on disclosure will then continue on an annual cycle.

### **3.1.3.3 All medicines on F2T**

Medicines on F2T will be subject to the following pricing arrangements:

- A one-off 25% mandatory price reduction will apply on 1 August 2008.
- The 12.5% price reduction policy will continue to apply, where relevant.
- Price reductions for medicines on F2T will flow on to all brands, forms and strengths of that medicine and to medicines that are interchangeable with that medicine at the patient level.
- For a defined list of interchangeable patented medicines on F2T, the 25% price reduction will be phased over the remaining patent life.
- Price disclosure:
  - Suppliers listing a new brand on or after 1 January 2011 must agree to disclose the actual market price as a condition of listing.
  - The first price reductions resulting from disclosure will take effect from 1 August 2012. Price reductions will reflect the weighted average disclosed price, taking account of volume and price information for each disclosing supplier.
  - The first disclosure of pricing information for an item will include at least 12 months of data. Pricing based on disclosure will then continue on an annual cycle.
- Pharmaceutical wholesalers and suppliers providing medicines direct to pharmacists will be required to supply products listed on F2T at the new price level two weeks before the 1 August 2008 price reductions. Pharmacists will continue to be reimbursed at the existing rate until the 1 August 2008 price reductions take effect.

### **3.1.3.4 F1 medicines entering F2 after 1 August 2007**

- Medicines moving from F1 will, as a general rule, join the F2A formulary.
- The 12.5% price reduction policy will continue to apply, where relevant.
- Staged price reductions of 2% will apply as per F2A up to and including 1 August 2010.
- Price disclosure:
  - Suppliers listing a new brand on or after 1 August 2007 must agree to disclose the actual market price as a condition of listing.
  - The first price adjustments resulting from disclosure will take effect from 1 August 2009. Price reductions will reflect the weighted average disclosed price, taking account of volume and price information for each disclosing supplier.
  - The first disclosure of pricing information for an item will include at least 12 months of data. Pricing based on disclosure will then continue on an annual cycle.

### **3.1.4 Price disclosure**

The following principles will apply:

1. Price disclosure arrangements will be triggered by the listing of a new brand of a listed medicine on or after 1 August 2007 (F2A) and on or after 1 January 2011 (F2T).
2. Unless a 12.5% or 2% price reduction applies, the initial listing price of the new brand will be the same price as other brands of that medicine. However, it will be a requirement of listing that the supplier of the new brand agrees to disclose to the Department of Health and Ageing the actual price at which they sell that brand to wholesalers and/or pharmacies.
3. All other suppliers of that medicine (brands, forms and strengths) will be invited to volunteer to disclose the prices at which they sell their medicine.

### **3.1.5 Calculation of the weighted average disclosed price**

The following principles will apply:

1. For the purposes of calculating the weighted average disclosed price, the disclosed price will be the ex-manufacturer price, i.e. excluding the wholesaler mark-up.
2. Price reductions as a result of price disclosure will reflect the weighted average disclosed price, taking into account volume and price information for each supplier of the medicine participating in the price disclosure arrangements.
3. Calculation of the weighted average disclosed price will exclude the first month of data following listing, although these data will still be collected. This is to ensure that the initial period of market competition does not unduly influence the weighted average.
4. The submission of price data to the Department will be at a specified time (expected to be on a quarterly basis).
5. No price reduction will be required if the weighted average disclosed price is less than 10% below the current PBS ex-supplier price.
6. If the weighted average disclosed price is 10% or more below the current PBS ex-supplier price, the weighted average disclosed price will become the basis for the government subsidy price for that medicine.
7. Suppliers and Approved Pharmacists will be advised of any price reduction resulting from disclosure six months before the price change takes effect.
8. Price changes resulting from disclosure will take effect either on 1 April or 1 August each year, depending on the item.

An example of how price disclosure would work is at [Attachment B](#).

### **3.1.6 Guarantee supply**

It is anticipated that legislation will protect supply by requiring the suppliers of new brands of medicines listing on the PBS to guarantee to supply for a minimum period and imposing penalties if they fail to meet this commitment.

## **3.2. Pharmacy and wholesaler support arrangements**

Pharmacists will be provided assistance to adjust to the new arrangements. These arrangements will remain in place until the end of 2010-11, and will take the form of:

- An incentive of \$1.50 (indexed by WCI9 or its replacement index) to dispense a substitutable, premium-free medicine on the F2 formulary from 1 August 2008. This

applies only to PBS subsidised medicines. Under-co-payment medicines and private scripts will not be eligible for this payment.

- The incentive will be a separately identified payment to pharmacists and will not form part of the PBS benefit for the dispensed item.
- The incentive will be calculated, processed and paid to pharmacists at the same time as the standard dispensing fee.
- An incentive of 40c for each prescription processed using PBS Online, from 1 July 2007.
  - Concessional Entitlement Validation (CEV) payments for Approved Pharmacists will continue to 30 June 2007. Approved Pharmacists that have completed the registration requirements for PBS Online by 1 July 2007 will continue to receive the 10 cent CEV payment until PBS Online is operational in that Approved Pharmacy or 31 December 2007, whichever is the sooner.
- Increases in pharmacy mark ups from 1 August 2008:

<b>Mark-up on Approved Price to Pharmacist</b>	<b>Value</b>
Up to and including \$30.00	15%
Between \$30.01 and \$45.00	\$4.50
Between \$45.01 and \$180.00	10%
Between \$180.01 and \$450.00	\$18.00
Between \$450.01 and \$1750.00	4%
Over \$1750.00	\$70.00

These changes do not apply to Highly Specialised Drugs. The Fourth Community Pharmacy Agreement Review of Section 100 of the *National Health Act 1953*<sup>19</sup> to be conducted in 2007 will consider the appropriateness of the existing arrangements for Highly Specialised Drugs.

- A 15c increase in the dispensing fee from 1 August 2008. A review of estimate differences, to be completed by the end of August 2007, will determine the precise quantum of the fee increase.
- Additional funding of \$69 million (including indexation) over three years will be added to the Community Services Obligation (CSO) Funding Pool to compensate pharmaceutical wholesalers for the impact on the wholesale margin resulting from the new pricing arrangements.

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<sup>19</sup> Refer clause 37 of the Fourth Community Pharmacy Agreement

### **3.3. Assistance for Software Vendors**

The Government will provide funding of up to \$20 million to support software vendors to meet the demand for an accelerated roll-out of PBS Online. Assistance will be provided to software vendors for site installation and ongoing support through a program administered by Medicare Australia.

### **3.4. Streamlining authority approvals for some medicines**

From 1 July 2007 the PBS-listed medicines that require an authority approval prior to prescribing will be separated into two categories:

1. Medicines that require approval from Medicare Australia prior to prescribing.
  - This category will include medicines for short term use, Section 100 medicines, requests for increased quantities and those medicines with an increased potential for misuse, abuse or adverse effects, such as narcotic medicines.
2. Medicines where the prescriber will not have to obtain approval from Medicare Australia prior to prescribing.
  - A prescriber will write the appropriate authority restriction code on each prescription for a medicine in this category.
  - This will not negate the need for the prescriber to ensure that patients receiving such medicines meet the prescribing requirements as specified by the Pharmaceutical Benefits Advisory Committee (PBAC) and specified in the PBS Schedule.
  - This will apply to medicines for the treatment of long term chronic conditions (such as diabetes and osteoporosis) where the patient and doctor are both very familiar with the condition and medication. Medicare Australia will undertake education and monitoring to ensure doctors are aware of the changes.

A list of PBS medicines and item codes for which the streamlined authority arrangements will apply was distributed to stakeholders on 20 December 2006.

### **3.5. Access to medicines working group**

A Medicines Australia and Department of Health and Ageing working group will be set up to consider issues regarding timely and appropriate access to new medicines for the PBS. The working group will establish a work plan and performance indicators for its work and report against these indicators. Other relevant bodies, such as the Therapeutic Goods Administration and the PBAC will be involved as required. The first meeting of this group is expected to take place in April 2007.

### **3.6. Generic medicines awareness campaign**

The Government is considering a public awareness campaign to promote the use of generic medicines. It would focus in particular on high users of the PBS, including concession card holders and those with chronic, long term conditions.

The campaign would commence in late 2007 or early 2008 and continue until 2009-10.

## **4. Implementation**

### **4.1 Stakeholder engagement**

The Department of Health and Ageing will establish a stakeholder reference group as a forum for providing updates to stakeholders on implementation progress and as a forum for seeking feedback on a range of issues.

The stakeholder reference group comprises representation from the Australian Medical Association, the Australia Self Medication Industry, the Generic Medicines Industry Association, Medicines Australia, the National Pharmaceutical Services Association, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia.

### **4.2 Key implementation dates**

A table showing the key implementation dates is at [Attachment C](#).

## Examples of how current reference pricing groups will be split across formularies<sup>20</sup>

### Reference Pricing Group L01 (1) – Antineoplastic agents (for the treatment of cancers):

Medicines in group	Formulary
Paclitaxel	F2A
Vinorelbine tartrate	F2A
Docetaxel	F1
Doxorubicin	F1
Gemcitabine	F1
Pemetrexed	F1
Topotecan	F1

### Reference Pricing Group N06 (3) – Psychoanaleptics (for the treatment of depression):

Medicines in group	Formulary
Citalopram hydrobromide	F2T
Fluoxetine hydrochloride	F2T
Fluvoxamine maleate	F2T
Mirtazapine	F2T
Moclobemide	F2T
Paroxetine hydrochloride	F2T
Sertraline hydrochloride	F2T
Escitalopram oxalate	F1

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<sup>20</sup> Schedule of Pharmaceutical Benefits, August 2006

Reboxetine mesilate

F1

## Example of how price disclosure would operate

Note: Assumes drug with single formulation, and all suppliers disclosing price information. Other disclosure scenarios (eg. where only one supplier discloses price information) will result in different actions.

### Price disclosure - example

1. Single brand medicine, PBS price (ex-manufacturer price) is \$100, originator sells with no discount – no disclosing brands

<b>PBS Price</b>	<b>Manufacturer</b>	<b>Actual supply price</b>	<b>Share of volume</b>
\$100.00	Originator	\$100.00	100%

2. New brand enters after patent expiry, with disclosure a condition of listing.

New brand offers 30% discount to pharmacy and secures 20% of volume.

In this scenario the originator also elects to disclose.

<b>PBS price</b>	<b>Manufacturer</b>	<b>Actual supply price</b>	<b>Share of volume</b>
\$100.00	Originator	\$100.00	80%
	New brand	\$70.00	20%
<b>WAP</b>			<b>\$94.00</b>

price difference 6.0%

Action: no price reduction

Weighted average pricing (WAP) is less than 10% below ex-manufacturer price, so there is no price reduction.

3. New brand gains 40% market share with 30% discounts to pharmacy.

<b>PBS price</b>	<b>Manufacturer</b>	<b>Actual supply price</b>	<b>Share of volume</b>
\$100.00	Originator	\$100.00	60%
	New brand	\$70.00	40%
<b>WAP</b>			<b>\$88.00</b>

price difference 12.0%

Action: price reduction

The WAP is 12% below the ex-manufacturer price, so a price reduction is triggered.

4. New brand gains 50% market share with 50% discounts to pharmacy

<b>PBS price</b>	<b>Manufacturer</b>	<b>Actual supply price</b>	<b>Share of volume</b>
\$100.00	Originator	\$100.00	50%
	New brand	\$50.00	50%
		<b>WAP</b>	<b>\$75.00</b>
		price difference	25.0%
		Action:	price reduction

The WAP is 25% below the ex-manufacturer price, so a price reduction is triggered.

## Key Implementation Dates

Year/ Activity	Formulary Changes	Legislation	Mandatory Price Reductions	Price Disclosure	Streamlining Authorities Arrangements	Pharmacy & Wholesaler Support Arrangements	Access to Medicines Working Group	Generic Medicines Awareness Campaign
2007	31 March 2007 Formulary lists finalised  1 August 2007 New formularies take effect	End of March / Early April 2007  Exposure draft released for comment  1 July 2007  Amendments to <i>NHA 1953</i>		1 August 2007  Agreement to price disclosure a condition of listing a new brand of an F2A medicine	1 July 2007  Implementation of new authority approval arrangements for some medicines	1 July 2007  PBS Online incentive payment for pharmacies processing prescriptions online  1 July to 31 December 2007  10 cent Concessional Entitlement Validation payment for pharmacies registered for PBS Online by 30 June 2007 but not yet processing prescriptions online	April 2007  First meeting	end 2007  Public awareness campaign commences.  (to be confirmed)
2008			1 August 2008  First F2A medicine 2% price reduction  F2T medicine 25% price reduction			1 August 2008  Increases in markups and dispensing fees  Premium-free medicine dispensing incentive  Increase to CSO funding pool		
2009			1 August 2009  F2A medicine 2% price reduction	1 August 2009  First F2A prices based on disclosure				

2010

**1 August 2010**

F2A medicine 2% price  
reduction

2011

**1 January 2011**

Agreement to price  
disclosure a condition of  
listing a new brand of an  
F2T medicine

2012

**1 August 2012**

First F2T prices based  
on disclosure