



Australian Government
Department of Health

SECRETARY

24 July 2015

Dr Kate Sullivan
Inquiry Secretary
Joint Committee of Public Accounts and Audit
Department of the House of Representatives
PO Box 6021
Parliament House ACT 2600

Dear Dr Sullivan

**Department of Health submission to the Joint Committee of Public Accounts and Audit
inquiry into the Australian National Audit Office's Report No. 25 2014-15
*Administration of the Fifth Community Pharmacy Agreement***

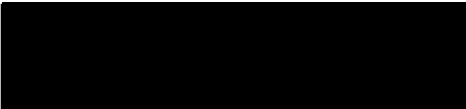
Thank you for the opportunity for the Department of Health (the Department) to provide this submission to the Joint Committee of Public Accounts and Audit (JCPAA) inquiry into the Australian National Audit Office (ANAO)'s Report No. 25 2014-15 *Administration of the Fifth Community Pharmacy Agreement* (the ANAO Report).

The Department supports the JCPAA in its important work. We trust that the attached submission provides a greater understanding of the Department's response to the ANAO Report for the Committee to consider.

A copy of the Department's submission is provided at Attachment A, and the Sixth Community Pharmacy Agreement is at Attachment B.

The Department looks forward to discussing this submission in more detail with the Committee on 13 August 2015.

Yours sincerely


Martin Bowles PSM

Attachment A

Department of Health Submission to the Joint Committee of Public Accounts and Audit (JCPAA) on the Australian National Audit Office (ANAO) Recommendations from the Administration of the Fifth Community Pharmacy Agreement report (ANAO Report)

The Department of Health (the Department) welcomes the oversight, assurance and advice that both the ANAO and the JCPAA bring to the Department.

The Department understands the recommendations of the Fifth Community Pharmacy Agreement (5CPA) audit and has implemented, or is implementing changes to address these recommendations in the development and continuing administration of the Sixth Community Pharmacy Agreement (6CPA) (a copy of the 6CPA is at Attachment B¹). The themes and recommendations of the ANAO Report have been reflected in the 6CPA, both in terms of the negotiation and agreement finalisation process, and in the 6CPA itself.

Further, the Department's approach to the design of the 6CPA reflects a number of themes taken from the ANAO Report. The underpinning is designed to ensure value for money and transparency in the funds paid to community pharmacy, by both Government and patients. Specific initiatives that reflect this include:

- Improving the transparency of financial commitments entered into by the Commonwealth by including estimated government expenditure and patient contributions for both subsidised and unsubsidised Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) prescriptions in the 6CPA (Table 2 clause 3.4);
- Annual reconciliations of expenditure in both script volumes and pharmacy programmes which will be reported back to Government (clause 5.4);
- De-linking pharmacy remuneration from the price of medicines, through the introduction of an Administrative Handling and Infrastructure fee as a specific component of the remuneration for dispensing (clause 3.4). *(This was noted by the ANAO as an opportunity not achieved by the 5CPA);*
- Re-focussing the Premium Free Dispensing Incentive (PFDI) to only apply in circumstances where there is an equivalent brand with a special patient contribution to the brand that is dispensed (clause 5.3);
- All pharmacy programmes under the agreement will now be the subject of independent evaluation, with cost-effective reviews undertaken for continuing programs and new and expanded programmes to proceed only where recommended by an independent health technology assessment body, such as the Medical Services Advisory Committee (MSAC) (clauses 6.1.3 and 6.1.6);
- A formal process will be undertaken to test the market for persons interested in, and capable of, providing administration support for the pharmacy programmes in the longer term, during the first year of the 6CPA (clause 6.2.2);
- Costs for administration of pharmacy programmes is clearly specified in the Agreement (clause 6.1.8); and,
- A comprehensive, independent and public review of pharmacy remuneration and regulation will be undertaken within the first two years of the 6CPA (clause 8).

A theme through a number of these initiatives has been the independent assessment of value for money. This will be applied as far as practicable to remuneration under the 6CPA including, pharmacy programmes on an on-going basis (clause 6.2.2), as well as the commencement of the comprehensive and independent review of pharmacy remuneration and

¹ All references to clauses or Appendices are referring to the relevant provision of the 6CPA.

regulation (including the Location Rules and wholesaler arrangements) (clause 8) by 1 September 2015. These activities will support value for money, as well provide an unprecedented level of transparency over pharmaceutical expenditure under 6CPA arrangements.

Pharmaceutical Benefits Division (PBD) and the Department more broadly has implemented changes to address the issues identified by the ANAO report, including imposition of a mandatory requirement for all PBD staff to undertake, and include records management training in, individual and team performance development. The Division has also rolled-out risk management training, with a focus on how to apply risk management in daily roles for all staff.

For recommendations relevant to the post-commencement administration of the 6CPA, significant steps have been undertaken to effect and embed changes consistent with the recommendations. For example, the Department is currently liaising with the Department of Veterans' Affairs and the Department of Human Services (DHS) for the purpose of addressing the collection, recording and sharing of information regarding payments to suppliers, so as to clearly identify the actual costs of medicines and the components of pharmacy remuneration. Further a working group has been established between the PBD and DHS, with a specific focus on data requirements and management, with the aim of better facilitating transparency and public reporting on the PBS, including the outcomes of the 6CPA by the Government.

The Department is committed to transparency and probity in public administration. This was reflected in our support and contribution of information in the 5CPA audit, the way in which we have used probity advisers in the 6CPA negotiations and the way in which we are continuing to work with the Pharmacy Guild of Australia and other stakeholders in the implementation of the 6CPA.

The Department is also committed to achieving strong outcomes for consumers, taxpayers, the industry and Government in the delivery of publicly funded medicines in the long-term. This has strongly influenced the way in which the initiatives and reforms of the PBS Access and Sustainability Package, including those which will be implemented though the 6CPA were designed, and is influencing the robust yet cooperative way in which we are engaging with all parts of the sector in the implementation of those initiatives.

The following table outlines in more detail, the specific actions that the Department has taken in response to each of the recommendations in the ANAO Report.

Recommendation from the ANAO Report	Status of Implementation of the Recommendation by the Department
Recommendation 1: To clarify the nature of financial commitments entered into by the Australian Government, the ANAO recommends that the Department of Health presents, in key documents, estimated government payments and patient payments for both subsidised and unsubsidised Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme medicines.	The Department has implemented system enhancements to its financial modelling software (PhRANCIS) to separately report on the cost to government, and the cost to patients, for PBS and RPBS medicines (subsidised and unsubsidised). Consistent with this, the 6CPA includes a breakdown of the estimated costs to the Government and to patients for payments made to pharmacies and wholesalers for medicines dispensed under the PBS and RPBS (Table 2 clause 3.4) as well as an estimate of patient payments for under co-payment scripts (clause 3.5). The signed copy of the 6CPA is publically available on the Department's website. From 1 January 2016, community pharmacies will be required to report to the Department the actual cost to the patient for all PBS and RPBS medicines priced below the general co-payment (clause 7.7). This will provide accurate expenditure data across the PBS and RPBS. A breakdown of the annual Government and patient costs for each of the remuneration and funding components of the 6CPA is expected to be included through one of the Department's key annual publications, (such as the Annual Report or Portfolio Budget Statements) and will also be available on the Department's website.
Recommendation 2: To provide assurance regarding the basis of costings for the next community pharmacy agreement, the ANAO recommends that the Department of Health applies the relevant forecast indexation factors released by the Department of Finance.	When the costings relating to the 6CPA were submitted by the Department to Department of Finance the most recent Department of Finance forecast indexation factors were used. The Department of Health worked closely with the Department of Finance throughout the costing of the 6CPA measures in relation to all aspects of the costings, particularly with respect to the use of relevant forecast indexation factors, having regard to the recommendations from the ANAO 5CPA Audit Report. The Department of Finance agreed with the costs provided by the Department of Health in relation to 6CPA measures (see costs described in Table 2, clause 3.4). In cases where cost models had to be reviewed, the Department of Health updated the indexation parameters to reflect the most current factors issued by the Department of Finance. For example, the cost models for the Discounting

Recommendation from the ANAO Report	Status of Implementation of the Recommendation by the Department
	Co-payments measure and the Freezing Indexation of the CSO measure were updated to reflect the most recent indexation parameters as soon as they became available.
Recommendation 3: To improve its ability to satisfy accountability requirements and capacity to protect the interests of the Commonwealth in the event of disputes or legal action, the ANAO recommends that the Department of Health: a) maintains an adequate record of the negotiation of the next community pharmacy agreement and related contracts; and b) reviews its internal guidance on record keeping for the negotiation of significant contracts and agreements.	In connection with part (a) of the recommendation: For the 6CPA negotiations, the Department appointed a full-time senior probity and risk officer (contracted from the private sector) who had experience in large-scale negotiations to support the negotiations with a range of probity services, including record keeping. Specific initiatives that were implemented include: • implementation of an agreed confidentiality process for all participants, internal and external; • establishment of specific, tailored record keeping guidelines for all participants in the 6CPA negotiation project, which participants were required to formally acknowledge; • maintenance of a risk register through the negotiations process, which included 'adequate record keeping' as a risk to be monitored; • appointment of a dedicated record keeping officer full-time within the 6CPA team to be responsible for record keeping; • for all negotiation and consultation meetings, the probity advisor was in attendance and a specific statement of outcomes was documented, and where relevant agreed with the parties to the meeting; • maintenance of tight security over all documentation through the project; • a final review of all negotiation and contract finalisation records was undertaken within reasonable time after the completion of contracts in order to provide assurance that the records were complete, structured sensibly and consistent with ANAO requirements. This continues into implementation. In connection with part (b) of the

Recommendation from the ANAO Report	Status of Implementation of the Recommendation by the Department
	recommendation: Portfolio Investment Division (PID) has completed a review of the internal guidance on record keeping for contracts and agreements across the Department. Implementation of the results of the review is in progress. Further, the Pharmaceutical Benefits Division specifically has implemented a range of training for its officers including risk management and record keeping and this training is now a required part of the Division's individual and team development programmes.
Recommendation 4: To improve the accuracy and transparency of reporting on Australian Government expenditure under the Pharmaceutical Benefits Scheme and the Repatriation Pharmaceutical Benefits Scheme, the ANAO recommends that the Departments of Health, Veterans' Affairs and Human Services liaise on the collection, recording and sharing of information regarding payments to suppliers, so as to clearly identify the actual costs of medicines and the components of pharmacy remuneration.	The Department is continuing to work with the Department of Veterans' Affairs and the Department of Human Services to improve data requirements in relation to expenditure under the PBS and the RPBS. A working group has been established between the Department and DHS, with a specific focus on data requirements and management, with the aim of better facilitating transparency and public reporting on the outcomes of the 6CPA by the Government. The working group's objectives include addressing the collection, recording and sharing of information regarding payments to suppliers, so as to clearly identify the actual costs of medicines to patients and the components of pharmacy remuneration including the cost of under co-payment prescriptions. The Department is aware that a key success factor will be the ability of pharmacies to provide this level of detail, and the Department of Human Services to collect and report at this level of granularity in relation to prescription or other data and is actively working with DHS to ensure this is realised. It is anticipated that this will be completed by the end of 2015-16.
Recommendation 5: In order to effectively discharge its advisory, accountability and contract management obligations in a timely manner, the ANAO recommends that the Department of Health reviews its record keeping arrangements for the Fifth Community Pharmacy Agreement and the next community pharmacy agreement.	The Department organised and implemented an internal review of its record keeping arrangements and processes in relation to the 5CPA in light of the ANAO's more detailed recommendations prior to the negotiation of the 6CPA to ensure that the lessons from the past informed processes for the 6CPA. The Department is currently establishing its operational and administrative arrangements for the administration of the 6CPA. This is being

Recommendation from the ANAO Report	Status of Implementation of the Recommendation by the Department
	supported by the independent probity and risk adviser engaged to advise on the negotiation process, in order to ensure continuity, consistency and fitness-for-purpose. As part of that design, relevant matters raised in the ANAO Report are specifically being addressed. Further, many of the principles described in the Department's implementation of recommendation 2 are being adopted and implemented. This includes: • the establishment and regular reminders to staff of record management disciplines; • the provision of record-keeping and risk-management training to staff; • specific assignment of responsibilities such as nominating individual staff members as 'record keepers' for large projects and negotiations such as the 6CPA; • introduction of a mandatory requirements for all PBD staff to undertake record managements training and this requirement is required to be included in individual and team performance development agreements; and • periodic review of records being kept. Further in 2015, the Department ran for all staff in the Pharmaceutical Benefits Division, refresher training in record keeping and records management. The design of detailed administrative implementation processes for specific components of the 6CPA management is currently underway, but will remain consistent with the matters and processes raised above.
Recommendation 6: To improve transparency in agreement-making, the ANAO recommends that the Department of Health documents anticipated levels of Australian Government funding for third party administration for the next community pharmacy agreement.	The level of third party administration funding for pharmacy trial programmes and community pharmacy programmes administered under the 6CPA is specified in the 6CPA as an amount not exceeding 3.5 per cent of the total funding allocation (clause 6.1.8). Further, the 6CPA has explicitly included a provision for an open market approach to potential providers of claims administration

Recommendation from the ANAO Report	Status of Implementation of the Recommendation by the Department
	support in connection with professional programs. This will provide increased transparency of the services provided and the market's ability to respond, whilst ensuring value for money. Planning for this tender process is underway, and will be undertaken during the 2015-16 financial year.
Recommendation 7: To improve transparency and the quality of program performance reporting, the ANAO recommends that the Department of Health reports annually on the actual cost of each major component of the Fifth Community Pharmacy Agreement and the next community pharmacy agreement, including pharmacy remuneration, CSO wholesaler payments and professional programs.	It is not possible to unilaterally amend the reporting requirements of the 5CPA. However, the Department will continue to provide any reports on components of the 5CPA as required by any outstanding reporting requirements, and improve this reporting where possible. The Department has focussed on ensuring better transparency and quality of programme reporting in the 6CPA, however. The Government, in its decision making regarding the 6CPA has specifically required the inclusion of a breakdown of expenditure by major programme component (Appendix B, clause 6.1). It is expected that the Department will report back to Government and publicly on expenditure related to these programme components on an annual basis. Further, 6CPA components will undergo formal and independent review; including pharmacy programmes (clause 6.1.3), pharmacy trial programmes (clause 6.1.6), regulation over community pharmacy (including Pharmacy Location Rules) and remuneration to community pharmacy for its dispensing role (clause 8).
Recommendation 8: To inform decision-making and the assessment of outcomes by stakeholders, the ANAO recommends that the Department of Health reviews performance reporting to improve alignment between the next community pharmacy agreement and the public reporting against the program objectives, deliverables and KPIs relating to the departments Program 2.1 and Program 2.2.	The Department has reviewed the current performance reporting structure to ensure the alignment between the 6CPA and public reporting against program objectives is improved. As a result, appropriate updates to the performance reporting structure for Programme Group 2.1 and 2.2 will be implemented as part of the 2015-16 Portfolio Additional Estimates Statements to align with this Recommendation. The measures associated with the 6CPA were announced after the 2015-16 Budget process, therefore they were not available for linking or updating the Department's objectives, deliverables and KPIs with respect to the 6CPA, in the 2015-16 Portfolio Budget Statements.

ATTACHMENT B

COPY OF THE 6th CPA



Australian Government
Department of Health

Sixth Community Pharmacy Agreement

The Honourable Sussan Ley MP, Minister for Health and Minister for Sport
on behalf of the **Commonwealth of Australia**
and

The Pharmacy Guild of Australia

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Sixth Community Pharmacy Agreement

Dated 24 May 2015

Parties

Name	The Honourable Sussan Ley MP Minister for Health and Minister for Sport on behalf of the Commonwealth of Australia
Short name	Commonwealth

Name	The Pharmacy Guild of Australia (ABN 84 519 669 143)
Address	Level 2, 15 National Circuit, Barton in the Australian Capital Territory
Short name	Guild

Background

- A. This Agreement is the Sixth Community Pharmacy Agreement entered into by the Minister for Health (acting on behalf of the Commonwealth of Australia) and the Pharmacy Guild of Australia for the purposes of section 98BAA of the *National Health Act 1953* (Cth) and for related purposes.
- B. Community pharmacy is an integral part of the Australian health care system through its role in the delivery of the PBS and related services.
- C. The parties have a common interest in:
- C.1 promoting the sustainability, efficiency and cost-effectiveness of the PBS within the broader context of health reform;
 - C.2 ensuring that community resources are appropriately directed across the health system; and
 - C.3 supporting the sustainability and viability of an effective community pharmacy sector.
- D. The PBS Access and Sustainability Package referred to in this Agreement seeks to establish pharmacy funding and medicines pricing arrangements and a range of sector improvements over 5 years to achieve the outcomes referred to in paragraph C above. The Package is intended to support the National Medicines Policy and appropriately balance the need to:
- D.1 ensure consumers can continue to have access to new and innovative PBS subsidised medicines at an affordable price that are necessary to maintain the health of the community;

- D.2 promote and improve the quality use of medicines; and
- D.3 ensure a cost-effective and sustainable PBS.
- E. The parties recognise that the purpose of the Package is to ensure longer term access to, and sustainability of, the PBS.

1. Definitions

- 1.1 In this Agreement, unless the contrary intention appears:

5CPA means the Fifth Community Pharmacy Agreement between the Commonwealth and the Guild dated 3 May 2010.

ACC means the Agreement Consultative Committee established under clause 5 of the 5CPA.

Act means the *National Health Act 1953* (Cth).

Admixed Ready-Prepared Pharmaceutical Benefit means an admixture of ready-prepared ingredients as specified in a determination made by the Minister under subsection 98C(1)(b) of the Act (as at the date of this Agreement being determination No. PB 119 of 2008).

Agreement means this Sixth Community Pharmacy Agreement.

AHI Fee means the administration, handling and infrastructure fee specified in Table 3.

approved ex-manufacturer price has the meaning given in Part VII of the Act.

approved pharmacist has the meaning given in Part VII of the Act.

approved supplier has the meaning given in Part VII of the Act.

Bill means the National Health Amendment (Pharmaceutical Benefits) Bill 2015.

Business Day means a day other than a Saturday, Sunday or public holiday in the Australian Capital Territory.

Commonwealth price means the price for a pharmaceutical benefit of a particular quantity or number of units as set out in the Determination.

Community Pharmacy Programmes has the meaning given in clause 6 and **CPP** has the same meaning.

CSO means the Community Service Obligation Funding Pool which is described in clause 5.1.

dangerous drug has the meaning given in the Determination.

Department means:

- (a) the Department of Health; or
- (b) any successor department or agency of the Commonwealth having responsibility for the administration of Part VII of the Act.

Department Representative means:

- (a) the person from time to time holding or acting in the position of First Assistant Secretary, Pharmaceutical Benefits Division within the Department; or
- (b) a person from time to time holding or acting in such other position notified by the Commonwealth to the Guild in writing from time to time.

Determination means the determination in force from time to time under subsection 98B(1)(a) of the Act.

Extemporaneously-Prepared Pharmaceutical Benefit or **EPPB** means a pharmaceutical benefit that is not a Ready-Prepared Pharmaceutical Benefit.

Ex-Manufacturer Price means, as applicable, the:

- (a) approved ex-manufacturer price; or
- (b) proportional ex-manufacturer price for a pack quantity (other than the pricing quantity),

of a listed brand.

Financial Year means each successive period of twelve months commencing on 1 July and ending on the immediately following 30 June.

Government Agency means any governmental, semi-governmental, administrative, fiscal, judicial or quasi-judicial body, department, commission, authority, tribunal, agency or entity.

Guild Representative means:

- (a) the person from time to time holding or acting in the position of Executive Director of the Guild; or
- (b) a person from time to time holding or acting in such other position notified by the Guild to the Commonwealth in writing from time to time.

Indexation Date means each 1 July during the Term commencing on 1 July 2016.

Indexed means indexed in accordance with clause 7.8.

Information includes any material, data, statement, information, estimate, forecast, prediction, advice, plan, drawing or idea.

listed brand has the meaning given in Part VII of the Act.

Location Rules means the rules determined by the Minister under section 99L of the Act.

Maximum Co-Payment means, as applicable:

- (a) the general patient reduced charge;
- (b) the concessional beneficiary charge; or
- (c) the general patient charge,

as applying from time to time under Part VII of the Act.

Minister means the Minister who administers the Act.

Package means the package of savings measures, remuneration and funding described in clause 3.

pack quantity has the meaning given in Part VII of the Act.

PBAC means the Pharmaceutical Benefits Advisory Committee established under section 100A of the Act.

PBS means the Pharmaceutical Benefits Scheme established under Part VII of the Act.

PGPA Act means the *Public Governance, Performance and Accountability Act 2013* (Cth).

pharmaceutical benefit has the meaning given in Part VII of the Act.

Premium Free Dispensing Incentive or **PFDI** means the incentive referred to in clause 5.3.

price to pharmacists has the meaning given in the Determination.

pricing quantity has the meaning given in Part VII of the Act.

proportional ex-manufacturer price has the meaning given in Part VII of the Act.

relevant quantity has the meaning given in Part 2 of the Determination.

Ready-Prepared Pharmaceutical Benefit or **RPPB** means a brand of a pharmaceutical item included in an operative determination in place under subsection 85(6) of the Act.

RPBS means the Repatriation Pharmaceutical Benefits Scheme established under the:

- (a) *Veterans' Entitlements Act 1986* (Cth);
- (b) *Military Rehabilitation and Compensation Act 2004* (Cth); and
- (c) *Australian Participants in British Nuclear Tests (Treatment) Act 2006* (Cth).

Safety Net means, as applicable:

- (a) the concessional beneficiary safety net; or
- (b) the general patient safety net,

as defined in Part VII of the Act.

Schedule equivalent has the meaning given in Part VII of the Act.

special patient contribution has the meaning given in Part VII of the Act.

Term means the term of this Agreement as set out in clause 2.

TGA means the Therapeutic Goods Administration that forms part of the Department.

Tribunal means the Pharmaceutical Benefits Remuneration Tribunal established under section 98A of the Act.

WCI9 means an index expressed as a percentage based on the change in wages and prices over the previous 12 month period, known as Wage Cost Index 9, as determined by the Department of the Treasury from time to time.

- 1.2 Unless otherwise defined in this Agreement, a term (including a term that is not capitalised) that is given a particular meaning in Part VII of the Act has the same meaning in this Agreement as it has in Part VII of the Act.

2. Term and commencement

2.1 Term of Agreement

Subject to clause 2.2, this Agreement commences on 1 July 2015 and expires on 30 June 2020.

2.2 Conditions precedent to commencement of Agreement

- 2.2.1 This clause 2.2 and clause 3.6 commence on the date of this Agreement.
- 2.2.2 This Agreement, other than this clause 2.2 and clause 3.6, will not commence until the following conditions precedent are satisfied, or waived by the Commonwealth in writing at its discretion:
- (a) the passage of the Bill through the Australian Parliament and the commencement of associated subordinate legislation in a form that will enable the achievement of the measures described in rows f, g, h, i and k in Table 1; and
 - (b) the achievement of amendments to the current deeds between the Commonwealth and CSO wholesalers to freeze the indexation of the CSO funding, as described in row c of Table 1.
- 2.2.3 The parties agree to use their respective best endeavours to ensure that the conditions in clause 2.2.2 are satisfied prior to 30 June 2015, with the exception of k in Table 1, which the Guild recognises is a matter for the Australian Government.
- 2.2.4 If the conditions in clause 2.2.2 are not satisfied or waived by 30 June 2015, any subsequent satisfaction or waiver of those conditions will not result in an extension of this Agreement beyond 30 June 2020.
- 2.2.5 If, by 25 June 2015, the parties consider that the Bill is unlikely to pass the Australian Parliament in the form required to satisfy the condition in clause 2.2.2(a) before 30 June 2015, the parties will consult with each other in relation to the arrangements after 30 June 2015.

3. PBS Access and Sustainability Package

- 3.1 The Package is intended to enable PBS and RPBS gross savings of \$6.6 billion (net savings of \$3.7 billion) over the Term through the implementation of the savings measures described in Table 1. The Package provides for an estimated increase in remuneration and funding to the community pharmacy sector and wholesaler distributors of pharmaceuticals during the Term, which the Commonwealth estimates to be \$3.2 billion over and above 5CPA levels.

Table 1: Savings measures

Savings measures	
a.	From 1 July 2015, an increase in the number of times a year that PBS medicine prices can change from three times per year (as applying under the 5CPA), to six times per year.
b.	From 1 July 2015, a re-focusing of the PFDI to only apply where there is a brand premium.
c.	From 1 July 2015, freezing of the indexation on the CSO for a period of five years.
d.	The substitution of biosimilar medicines at the pharmacy level based on the clinical recommendations of the PBAC.
e.	From 1 January 2016, delisting of selected over-the-counter medicines from the PBS, based on the clinical recommendations of the PBAC.
f.	From 1 January 2016, an expansion of the PBS early supply provision, 'Safety Net 20 Day rule', so that it applies to all PBS medicines where it is considered appropriate for the patient population, based on the advice of the PBAC.
g.	From 1 April 2016, the component drug price disclosure arrangements under the Act are to be applied to F2 combination medicines.
h.	From 1 April 2016, a one-off statutory price reduction of 5 per cent to all brands of pharmaceutical items on the F1 formulary once the drug has been listed on the PBS for at least five years.
i.	From 1 October 2015, originator brands will be removed from the calculation of the weighted average disclosed price of medicines under price disclosure arrangements for those medicines that have been listed on the F2 formulary for three years or more.
j.	From 1 July 2016, a transfer of the distribution of National Diabetes Services Scheme products from Diabetes Australia to pharmaceutical wholesalers through the existing CSO arrangements.
k.	From 1 January 2016, approved pharmacists may (but are not obliged to) discount the PBS patient co-payment by a maximum of \$1 per PBS supply.

3.2 The savings measures in:

- 3.2.1 rows a and b in Table 1 will be implemented under this Agreement;
- 3.2.2 rows f, g, h, i and k in Table 1 are contingent upon the passage of the Bill through the Australian Parliament and the commencement of associated subordinate legislation;
- 3.2.3 rows c and j in Table 1 require the agreement and cooperation of other participants in the pharmaceutical supply chain; and
- 3.2.4 rows d and e in Table 1 will be achieved under existing Part VII of the Act.

3.3 Once the Bill passes through the Australian Parliament, remuneration and funding of approved pharmacists and others in the pharmaceutical supply chain will be restructured resulting in what the Commonwealth estimates to be \$18.9 billion in remuneration over the Term, comprising:

- 3.3.1 Commonwealth contributions of \$15.5 billion; and

3.3.2 patient contributions of \$3.4 billion,

as set out in Table 2.

- 3.4 The Commonwealth contributions in Table 2 include payments to pharmacists and wholesalers for medicines dispensed under the PBS and RPBS. A key element of the remuneration described in Table 2 is the new AHI Fee that forms part of the Commonwealth price. The AHI Fee replaces the former pharmacy mark-up and represents a significant change to the basis upon which community pharmacies are remunerated. Both parties recognise that the introduction of the AHI Fee (and de-linking pharmacy remuneration from medicine pricing) is intended to support the sustainability of the community pharmacy sector while removing a barrier to future PBS reform.

Table 2: Components of the remuneration and funding

Component	Contributor	\$million (estimated)
Pharmacy remuneration for dispensing, including dispensing fee, AHI Fee and dangerous drug fee	Commonwealth	11,112
	Patient	3,025
Premium Fee Dispensing Incentive funding	Commonwealth	655
	Patient	N/A
Community Pharmacy Programmes	Commonwealth	1,263
	Patient	As set under CPPs
Remuneration for wholesalers to hold and deliver medicines to approved pharmacists (excluding the CSO)	Commonwealth	1,414
	Patient	385
CSO funding pool	Commonwealth	976
	Patient	N/A
Fees for CSO distributors to distribute National Diabetes Services Scheme products	Commonwealth	28
	Patient	N/A
Fees for pharmacy to distribute National Diabetes Services Scheme products	Commonwealth	28
	Patient	No additional patient charge
Total	Commonwealth	15,476
	Patient	3,410
	Total	18,886¹
Chemotherapy compounding fees ²	Commonwealth	372

- 3.5 The Commonwealth also estimates that community pharmacy will receive up to a further \$4.8 billion from dispensing pharmaceutical items that are priced below the Maximum Co-Payment.

- 3.6 Recognising the significance of the Package and associated reforms, the Guild will provide all reasonable assistance to facilitate and support the measures in the Package, with the exception of row k of Table 1, which the Guild recognises is a matter for the Australian Government. The Guild will communicate positively with its members and the public about the benefits of the Package as a whole.

¹ This excludes remuneration when community pharmacies dispense medicines under Section 100 special arrangements.

² Compounding fees will be paid directly to chemotherapy compounders, who may not be approved suppliers.

- 3.7 The Guild acknowledges that there are a range of savings measures contained in the Package. No compensation will be considered by the Australian Government, or payable by the Commonwealth, in relation to these savings measures.

4. Commonwealth price

4.1 Purpose

This clause 4 is an agreement between the Minister and the Guild for the purposes of subsection 98BAA(1) of the Act.

4.2 Commonwealth price

4.2.1 The Commonwealth price has been set on the basis of a formula which comprises the Ex-Manufacturer Price plus allowances for the supply of PBS medicines over and above that price.

4.2.2 In agreeing to a Commonwealth price for a particular medicine, the Commonwealth includes allowances for:

- (a) the cost to the approved pharmacist (price to pharmacists), which includes two components:
 - (i) production of the medicine (Ex-Manufacturer Price); and
 - (ii) wholesale distribution of the medicine;
- (b) the administration, handling and storage costs entailed in dispensing medicines by the pharmacy, including associated infrastructure; and
- (c) a pharmacist's specialised skills in dispensing the medicines.

4.2.3 The components of the Commonwealth price during the Term, as agreed by the Commonwealth and the Guild, are as set out in Table 3 below. Additional detail on how these components are defined, calculated and applied will be set out in the Determination.

Table 3: Components of the Commonwealth price

Payment type	Date of effect	Value of payment	
wholesale mark-up ⁽¹⁾ (for RPPBs)	1 July 2015	Where the Ex-Manufacturer Price is up to and including \$930.06	7.52% of the Ex-Manufacturer Price per dispense
		Where the Ex-Manufacturer Price is over \$930.06	\$69.94 per dispense

⁽¹⁾ The wholesale mark-up for a pack quantity of a listed brand is calculated using the relevant quantity.

Payment type	Date of effect	Value of payment	
administration, handling and infrastructure fee	1 July 2015	For a pack quantity of a listed brand with a price to pharmacists less than \$180	\$3.49 per dispense
		For a pack quantity of a listed brand with a price to pharmacists from \$180 to \$2,089.71	\$3.49, plus 3.5% of the amount by which the price to pharmacists exceeds \$180, per dispense
		For a pack quantity of a listed brand with a price to pharmacists more than \$2,089.71	\$70.00 per dispense
dispensing fee (for RPPBs)	1 July 2015	\$6.93 per dispense	
dispensing fee (for EPPBs)	1 July 2015	Dispensing fee for RPPBs, plus \$2.04, per dispense	
dangerous drug fee (for RPPBs)	1 July 2015	\$2.91 per dangerous drug dispensed	

4.2.4 The:

- (a) AHI Fee;
- (b) dispensing fee for RPPBs; and
- (c) dangerous drug fee for RPPBs,

as described in Table 3, will each be Indexed on the Indexation Date.

4.2.5 The wholesale mark-up set out in Table 3 will not be Indexed during the Term.

4.2.6 The only change to EPPB pricing under this Agreement is the introduction of the AHI Fee.

4.3 PBS price changes

PBS price changes will occur 6 times a year, on 1 February, 1 April, 1 June, 1 August, 1 October and 1 December. The price change dates applying under Division 3B of Part VII of the Act are not changed by this clause 4.3.

4.4 Wholesaler remuneration

The comprehensive review referred to in clause 8 will include a review of the remuneration paid to wholesale distributors of pharmaceuticals. The findings of the comprehensive review may result in changes to the remuneration of wholesale distributors of pharmaceuticals during the Term. The Commonwealth will consult with wholesale distributors of pharmaceuticals, and other stakeholders (including the Guild) as determined by the Minister, on any changes to wholesaler remuneration contemplated as a result of the comprehensive review. Should the recommendations of the review identify that the system is inadequately remunerating wholesaler distributors of pharmaceuticals, or such wholesalers will not be

viable in the medium to long term, the remuneration arrangements for the pharmaceutical wholesale sector will be considered by the Commonwealth.

5. CSO and other charges and incentives

5.1 Community Service Obligation Funding Pool

5.1.1 The Commonwealth has established the CSO to:

- (a) ensure that all approved pharmacists are able to obtain timely supply of section 85 PBS medicines, irrespective of:
 - (i) the size or location of the pharmacy;
 - (ii) the breadth of the PBS product range;
 - (iii) the cost of the PBS medicines; or
 - (iv) the cost of their distribution and supply to the pharmacy;
- (b) ensure that all Australians have access to the PBS medicines they require, regardless of the cost of the medicine, or where they live; and
- (c) remunerate eligible wholesale distributors of pharmaceuticals for the additional cost they incur in providing PBS medicines, as compared to those wholesalers who choose to distribute and supply a lesser range of PBS medicines.

5.1.2 The value of the CSO in each Financial Year during the Term will be up to \$195,220,000. The CSO will not be indexed during the Term.

5.1.3 The Commonwealth intends to undertake a formal process to appoint CSO distributors during the first Financial Year of the Term. Distributors will be required to satisfy CSO eligibility requirements, as determined by the Commonwealth, and as set out in the documentation released by the Commonwealth when calling for such applications.

5.1.4 The Commonwealth will:

- (a) consider the scope of future CSO service level arrangements; and
- (b) consult with relevant stakeholders (including the Guild) as it considers appropriate regarding any revised CSO service level arrangements,

prior to undertaking any formal process to appoint CSO distributors.

5.1.5 The cost of administering the CSO will be met from within the CSO. The Commonwealth intends to undertake a formal competitive process to appoint a CSO administrator during the first Financial Year of the Term. Actual CSO administration costs during the Term will be identified as part of that competitive process.

5.1.6 The Commonwealth intends to pursue administrative efficiencies as part of the CSO arrangements during the Term. This may include simplifying reporting requirements and other regulatory reforms that reduce the administrative burden on the wholesale distributors of pharmaceuticals, and reflect competitive business practices.

- 5.1.7 It is the common intention of the parties that CSO distributors:
- (a) will supply section 85 medicines under the CSO arrangements at or below the:
 - (i) price to pharmacists; or
 - (ii) the claimed price plus the wholesale mark-up (specified in Table 3);
 - (b) may not impose new or additional fees for the supply of section 85 medicines under the CSO arrangements that were not specifically allowed for under the CSO arrangements as at 1 July 2015; and
 - (c) may charge new or additional fees for section 85 medicines that are requested by the pharmacy to be supplied in a manner inconsistent with the CSO arrangements as they exist from time to time.
- 5.1.8 Without limiting clause 5.1.4, the Commonwealth will consult with the Guild prior to entering into any arrangements with CSO distributors that are inconsistent with the common intention of the parties set out in clause 5.1.7.

5.2 Charges for pharmaceutical benefits below Maximum Co-Payment

- 5.2.1 This clause 5.2 is an agreement between the Minister and the Guild for the purposes of subsection 84C(9) of the Act. Nothing in this clause 5.2 is intended to limit any other section of the Act, including any section which prescribes when amounts are, or are not to be, counted as accumulating towards a patient's Safety Net.
- 5.2.2 For Ready-Prepared Pharmaceutical Benefits that are priced below the Maximum Co-Payment (other than Admixed Ready-Prepared Pharmaceutical Benefits), approved pharmacists can charge the sum of:
- (a) the Commonwealth price;
 - (b) \$1.17; and
 - (c) a further additional patient charge amounting to 10% of the Maximum Co-Payment plus 50 cents,
- provided that such a sum does not exceed the Maximum Co-Payment.
- 5.2.3 For Extemporaneously-Prepared Pharmaceutical Benefits and Admixed Ready-Prepared Pharmaceutical Benefits that are priced below the Maximum Co-Payment, approved pharmacists can charge the sum of:
- (a) the Commonwealth price;
 - (b) \$1.53; and
 - (c) a further additional patient charge amounting to 10% of the Maximum Co-Payment plus 50 cents,
- provided that such a sum does not exceed the Maximum Co-Payment.
- 5.2.4 The additional patient charges referred to in clauses 5.2.2(c) and 5.2.3(c) will not accumulate, and must not be recorded by approved pharmacists as accumulating, towards consumers' Safety Nets.

- 5.2.5 Approved pharmacists must make consumers aware of any patient charges referred to in clauses 5.2.2(c) and 5.2.3(c) and of the fact that they are not Commonwealth initiated.
- 5.2.6 The fees specified in clauses 5.2.2(b) and 5.2.3(b) will be adjusted annually on 1 July during the Term based on changes in WCI9.

5.3 Premium Free Dispensing Incentive

- 5.3.1 As at 1 July 2015, the PFDI is \$1.72. The PFDI will be Indexed annually on the Indexation Date.
- 5.3.2 The PFDI will be paid to an approved supplier (except an approved hospital authority for a public hospital) where the Commonwealth is satisfied that such approved suppliers have dispensed a pack quantity of a listed brand (**Dispensed Medicine**) in all the following circumstances:
 - (a) the Dispensed Medicine is Schedule equivalent to one or more other listed brands;
 - (b) one or more pack quantities of the listed brands that are Schedule equivalent to the Dispensed Medicine have a special patient contribution;
 - (c) the pack quantity of the Dispensed Medicine does not have a special patient contribution; and
 - (d) before the addition of the PFDI, the Commonwealth price of the pack quantity of the Dispensed Medicine already exceeds the Maximum Co-Payment.
- 5.3.3 Where payable, the PFDI is separate from, and in addition to, the Commonwealth price.

5.4 Annual community pharmacy and wholesaler reconciliation

- 5.4.1 As soon as practicable following the end of each Financial Year during the Term (**Relevant Financial Year**), except the last Financial Year, the Department will conduct, in consultation with the Guild, an annual reconciliation of actual versus estimated total community pharmacy and wholesaler remuneration, based on the actual PBS and RPBS prescription volumes in the Relevant Financial Year, as compared to the PBS and RPBS prescription volume estimates specified in Appendix A for that Financial Year.
- 5.4.2 Following the reconciliation described in clause 5.4.1, the Minister will report to the Australian Government any prescription volume variation for a Financial Year that is higher or lower than the percentage materiality threshold agreed by the parties under clause 5.4.3. If the Australian Government agrees, a risk sharing arrangement would be designed and implemented to address the identified variance.
- 5.4.3 The parties will seek to agree, on or before 31 May 2016, a materiality threshold (to be expressed as a percentage) to be applied in relation to any variance between actual and estimated PBS and RPBS prescription volumes. In the event that the parties are unable to agree the materiality threshold on or before 31 May 2016, either party may refer the issue for resolution in accordance with the process set out in clause 10.1.

- 5.4.4 The actual prescription volumes used for the purposes of the reconciliation described in clause 5.4.1 will be derived from the data sources specified in Appendix A.

6. Community Pharmacy Programmes

6.1 Allocation of Community Pharmacy Programme funding

- 6.1.1 The Commonwealth will make available up to \$1.26 billion in funding for evidence-based, patient-focused professional pharmacy programmes and services (**Community Pharmacy Programmes**) over the Term.
- 6.1.2 Funding for Community Pharmacy Programmes will be as approved by the Minister, following consultation by the Department with a range of stakeholders and bodies (including the Guild) as required, and is expected to:
- (a) be at a level of \$613 million over the Term as continued investment in a range of Community Pharmacy Programmes;
 - (b) be at a level of \$50 million over the Term as funding for a Pharmacy Trial Programme (**PTP**) relating to Community Pharmacy Programmes which are referred to in clause 6.1.4; and
 - (c) include, subject to clauses 6.1.4 and 6.1.6, access to additional funding of up to \$600 million over the Term to support new and expanded Community Pharmacy Programmes, and which are intended to be delivered through community pharmacies (excluding unapproved pharmacies).
- 6.1.3 The Community Pharmacy Programmes set out in Appendix B will continue from 1 July 2015 until the Minister determines otherwise and will be subject to a cost-effectiveness assessment by an independent health technology assessment body (such as the Medical Services Advisory Committee or the PBAC) as determined by the Minister.
- 6.1.4 The PTP will be established by the Commonwealth to trial new and expanded Community Pharmacy Programmes which seek to improve clinical outcomes for consumers and/or extend the role of pharmacists in the delivery of primary healthcare services through community pharmacy. In determining priorities for the PTP and the trials to be undertaken, the Department will consult extensively with the Guild and a range of stakeholders and bodies as required. This process will inform recommendations to the Minister on PTP activities to be funded by the Commonwealth, and the quantum of funds to be allocated on an annual basis.
- 6.1.5 It is intended that a particular focus of the new, continuing and expanded Community Pharmacy Programmes will be those which benefit:
- (a) Aboriginal and Torres Strait Islander peoples; and
 - (b) consumers in rural and remote areas.
- 6.1.6 Any funding for a trialled Community Pharmacy Programme after the conclusion of the PTP for that Community Pharmacy Programme will be contingent on:
- (a) a recommendation to proceed with the programme or service by an independent health technology assessment body (such as the Medical Services Advisory Committee or the PBAC) determined by the Minister; and

- (b) the programme or service satisfying funding priorities determined by the Minister.
- 6.1.7 Both parties acknowledge that input and support in the design and implementation of Community Pharmacy Programmes is expected to utilise involvement from a range of stakeholders and bodies from the public, pharmacy, pharmaceutical and medical sectors.
- 6.1.8 The cost of administering the PTP (including any approved communication activities) and any new or continuing Community Pharmacy Programmes will be drawn from the programme funding allocated by the Commonwealth and is expected to be up to 3.5 per cent of the total Community Pharmacy Programmes funding allocation under clause 6.1.2.
- 6.1.9 The Guild acknowledges that:
 - (a) the Australian Government requires the achievement of real improvement in patient access to community pharmacies (including through increased opening hours) under Community Pharmacy Programmes; and
 - (b) funding for existing and any new or expanded Community Pharmacy Programmes under this Agreement will be contingent on the Guild and approved pharmacists actively working with the Department over the first Financial Year of the Term, and then on an ongoing basis, to achieve such improvement, including setting targets for improvement in the second Financial Year of the Term and beyond.
- 6.1.10 Subject to compliance with all applicable:
 - (a) laws, including the PGPA Act;
 - (b) subordinate legislation; and
 - (c) programme objectives, deliverables, reporting requirements and key performance indicators,and the approval of the Australian Government, the parties will use their best endeavours to ensure that all funds allocated by the Commonwealth to individual Community Pharmacy Programmes are fully and appropriately expended.

6.2 Programme governance

- 6.2.1 Subject to compliance with all requirements under the PGPA Act and its subordinate legislation, the current agreement between the Commonwealth and the Guild for the administration of existing Community Pharmacy Programmes will continue for the first Financial Year of the Term.
- 6.2.2 The Guild acknowledges that the Department intends to ascertain through a formal process whether there are any persons interested in, and capable of, providing administration support in respect of the Community Pharmacy Programmes after the end of the first Financial Year of the Term. Any such process and subsequent engagement of one or more persons will be conducted in accordance with all standards of accountability required of the Department and relevant officials under the PGPA Act, including as set out in the Public Governance, Performance and Accountability Rule 2014, the Commonwealth Procurement Rules and the Commonwealth Grant Rules and Guidelines. The Guild may submit a response to any such formal process.

- 6.2.3 Any new or continuing arrangements entered into by the Commonwealth for the administration of Community Pharmacy Programmes will include clear programme objectives, deliverables, reporting requirements and key performance indicators so that the Commonwealth can assess the outcomes of such Community Pharmacy Programmes and their value to the Australian community.

7. Other arrangements

7.1 eHealth

- 7.1.1 Both parties will work together on an ongoing basis during the Term to encourage approved pharmacists to:
- (a) continue to drive greater uptake of the personally controlled electronic health records; and
 - (b) meet all relevant requirements of the eMedications Management Functional Framework (or equivalent requirements) as they are published by NEHTA from time to time.
- 7.1.2 In this clause 7.1:

personally controlled electronic health record has the meaning given in the *Personally Controlled Electronic Health Records Act 2012* (Cth) or means an equivalent record.

NEHTA means National E-Health Transition Authority Ltd ACN 114 638 336 or its successor.

7.2 Location Rules

- 7.2.1 The Location Rules are not altered by this Agreement.
- 7.2.2 The Location Rules will be continued beyond their current expiry date of 30 June 2015 until 30 June 2020.
- 7.2.3 The parties acknowledge that the Bill contains amendments to the Act to extend the sunset dates of 30 June 2015 in sections 90(3C) and 99Y of the Act to 30 June 2020.

7.3 Availability of PBS medicines in pharmacy

The Guild agrees 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 where the demand is, or should reasonably have been, anticipated by the relevant approved pharmacist.

7.4 New National Diabetes Services Scheme arrangements

- 7.4.1 The Commonwealth intends that from on or about 1 July 2016, product supply and delivery under the Commonwealth funded National Diabetes Services Scheme (NDSS) will be redirected through the established wholesale distribution network to approved pharmacists.
- 7.4.2 Under these new arrangements, approved pharmacists that supply NDSS products are intended to receive a payment of \$1 for each NDSS product supplied. The amount of this payment will remain fixed for the Term, with no indexation applied.

- 7.4.3 These arrangements will also include a \$1 per unit fee for CSO distributors for each NDSS product supplied through the CSO arrangements. The amount of this payment will also remain fixed for the Term, with no indexation applied.

7.5 Chemotherapy

- 7.5.1 The Commonwealth intends to reform the current arrangements for the payment of fees for chemotherapy infusions prepared under special arrangements made by the Minister under section 100 of the Act.

- 7.5.2 It is proposed that under the new arrangements:

- (a) fees would be paid directly to chemotherapy compounders under new arrangements determined by the Minister; and
- (b) the fees paid to compounders who are licensed by the TGA to undertake such compounding would be higher than those paid to compounders who are not licensed by the TGA, recognising that TGA licensed compounders incur additional costs in complying with the TGA's licensing requirements, as compared to chemotherapy compounders who are not TGA licensed.

- 7.5.3 Under this arrangement, the fees paid to compounders would be \$40 for non-TGA licenced providers and \$60 for TGA licenced providers (**Compound Fees**). Compound Fees will remain fixed for the Term, with no indexation applied.

- 7.5.4 The Commonwealth will implement changes to bring about the payment of Compound Fees in consultation with chemotherapy compounders and approved pharmacists who supply chemotherapy infusions.

7.6 Obligations of approved suppliers

The Guild will use its best endeavours to ensure that approved suppliers comply with their obligations as set out in this Agreement.

7.7 Data from approved suppliers

- 7.7.1 Approved suppliers must provide the Commonwealth with data on each PBS or RPBS prescription supplied by an approved supplier that is priced below the Maximum Co-Payment, including:

- (a) the patient's name;
- (b) the patient's Medicare number;
- (c) information about the prescription (including the date of prescribing and supply, the PBS or RPBS code number, the listed brand, the quantity dispensed and the number of repeats);
- (d) the PBS prescriber number;
- (e) the approved supplier number; and
- (f) the price charged by the approved supplier.

7.7.2 Each time an approved supplier allows a discount to the patient co-payment, as permitted under the Act, in relation to a PBS or RPBS prescription (**Co-Payment Discount**), the approved supplier must provide the Commonwealth with details of:

- (a) the amount of the Co-Payment Discount;
- (b) the patient's name;
- (c) the patient's Medicare number;
- (d) information about the prescription (including the date of prescribing and supply, the PBS or RPBS code number, the listed brand, the quantity dispensed and the number of repeats);
- (e) the PBS prescriber number;
- (f) the approved supplier number; and
- (g) the price charged by the approved supplier.

7.8 Indexation

7.8.1 Where this Agreement specifies that an amount is to be Indexed under this Agreement, the amount will be varied on the Indexation Date by applying the following formula:

$$\text{New Amount} = \text{Last Amount} \times \left(\frac{\text{MRIN}}{\text{LIN}} \right)$$

7.8.2 In this clause 7.8:

index number, in relation to a quarter, means the All Groups Consumer Price Index number that is the weighted average of the 8 capital cities and is published by the Australian Statistician in respect of that quarter.

Last Amount means the amount immediately before the relevant Indexation Date.

LIN means the quarterly index number, as published for the same quarter as the MRIN in the year immediately preceding the year of the MRIN.

MRIN means the most recently published quarterly index number as at the relevant Indexation Date.

New Amount means the amount, rounded to the nearest cent, on and from the relevant Indexation Date.

7.9 Payment times

7.9.1 The Guild and its members recognise that, by submitting a PBS or RPBS claim, approved suppliers are acknowledging that they have complied with all relevant Commonwealth, State and Territory legislative requirements for the dispensing of a PBS or RPBS medicine, including:

- (a) the codes, guidelines and policies established by the Pharmacy Board of Australia (or any other registering authority);

- (b) the codes, guidelines, professional practice standards and competency standards established by the Pharmaceutical Society of Australia;
 - (c) the standards and requirements as established by other authorities, including the TGA and Society of Hospital Pharmacists (as applicable to specialised areas of practice);
 - (d) any regulations or requirements as established by States and Territories with respect to one or more of the registration, practice or handling of medicines established within that State or Territory;
 - (e) all applicable State, Territory and Commonwealth laws with respect to the conduct of their profession; and
 - (f) any other requirements not stated above but that are covered by the *National Health (Pharmaceutical Benefits) (Conditions of approval for approved pharmacists) Determination 2007*.
- 7.9.2 Subject to circumstances beyond the Commonwealth's control, payments for payable prescriptions transmitted and assessed online will be processed within 9 to 16 days from receipt of electronic assessment.

8. Comprehensive review of pharmacy remuneration and regulation

- 8.1 The Commonwealth will appoint a panel of three eminent independent reviewers to conduct a comprehensive review of matters including:
- 8.1.1 remuneration for supplying government subsidised medicines; and
 - 8.1.2 rules about the location of pharmacies.
- 8.2 The comprehensive review will be based on specific terms of reference determined by the Minister. The Minister will determine the terms of reference for the comprehensive review after consultation with the Guild. It is anticipated that the review:
- 8.2.1 will consider:
 - (a) the Location Rules, and their role in supporting access to PBS medicines;
 - (b) remuneration of community pharmacy, both in terms of the level of funding and how it is provided to pharmacies for the dispensing of PBS medicines; and
 - (c) PBS supply chain arrangements, such as the logistics and distribution of medicines, including their regulatory requirements and cost to the Commonwealth and the Australian community,including how the matters set out in clauses 8.2.1(a), 8.2.1(b) and 8.2.1(c) contribute to patient health outcomes and improve the quality use of medicines; and
 - 8.2.2 provide recommendations as to:
 - (a) how to promote the most effective models for facilitating access to PBS medicines for consumers; and

- (b) any regulatory changes that may be required to promote high standards of delivery and accountability amongst community pharmacies and other persons receiving funding under the PBS and this Agreement, including wholesalers.
 - 8.3 It is intended that the comprehensive review will commence on or about 1 September 2015 and will deliver its final report by 1 March 2017.
 - 8.4 The basis of community pharmacy remuneration specified in Table 3 and the PFDI will not be changed during the Term based on the outcomes of the comprehensive review.
 - 8.5 The Location Rules will not be changed during the Term based on the outcomes of the comprehensive review or otherwise, except with the express written agreement of the parties.
 - 8.6 Changes to arrangements with the wholesale distributors of pharmaceuticals based on the outcomes of the comprehensive review may be agreed between the Commonwealth and the relevant wholesalers during the Term.
 - 8.7 The Guild undertakes to provide its full support to the comprehensive review, including by:
 - 8.7.1 providing such Information within its possession or control as is requested by the reviewers; and
 - 8.7.2 taking all reasonable steps to ensure that its members provide such Information within their possession or control as is requested from them by the reviewers,provided that the Guild or its members (as applicable depending on who is being asked to provide the Information) have no legitimate obligation of confidence to a third party in respect of such Information. Nothing in this clause 8.7 requires the Guild or its members to provide Information that they are not lawfully entitled to disclose under the Australian Privacy Principles set out in the *Privacy Act 1988* (Cth).
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9. Governance and consultation

9.1 Agreement consultation framework

- 9.1.1 The Department is responsible for the management, monitoring and evaluation of all aspects of the 6CPA. This will be undertaken consistent with the framework established by the PGPA Act and government best practice in order to effectively discharge advisory, accountability, governance, administration, performance reporting and contract management obligations.
- 9.1.2 The decisions of the Department may be informed through consultation with one or more stakeholders as appropriate (in particular the Guild), which may include time limited working groups or multilateral forums.
- 9.1.3 During the first 6 months of the Term:
 - (a) the ACC will continue on the same basis as it did immediately prior to the end of the 5CPA; and
 - (b) the parties will consult in relation to establishing governance arrangements:
 - (i) that will enable the Department and the Guild to effectively oversee the 6CPA (including to enable the Department to discharge its

responsibilities described in clause 9.1.1 and undertake the consultation described in clause 9.1.2); and

(ii) that will apply thereafter for the remainder of the Term.

9.1.4 The parties acknowledge that:

- (a) Community Pharmacy Programmes will be subject to a cost-effectiveness assessment by an independent health technology assessment body (such as the Medical Services Advisory Committee or the PBAC), as determined by the Minister;
- (b) the remuneration for supplying government subsidised medicines and rules about the location of pharmacies will be evaluated as part of the comprehensive review described in clause 8; and
- (c) there will be an annual reconciliation under clause 5.4 of total pharmacy and wholesaler remuneration based on prescription volumes,

the results of which will be made publicly available.

9.2 Pharmaceutical Services Federal Committee of Inquiry

The Guild acknowledges that the Minister intends to establish a Pharmaceutical Services Federal Committee of Inquiry under section 113 of the Act to investigate allegations of non-compliance with PBS approval requirements.

10. General matters

10.1 Issue resolution

10.1.1 Any issue or dispute arising in connection with, or from the operation of, this Agreement (other than under clause 4) will be resolved as follows:

- (a) the party with the issue or dispute will send to the other party a notice setting out the nature of the issue or dispute (**Notice of Dispute**);
- (b) the Department Representative and the Guild Representative will then try to resolve the issue or dispute by direct negotiation;
- (c) if the issue or dispute is not so resolved by direct negotiation under clause 10.1.1(b) within 20 Business Days from the date the Notice of Dispute is given, either party may refer the matter for direct negotiation between the Minister and the National President of the Guild; and
- (d) if the dispute is not resolved under clause 10.1.1(c), either party may immediately request the dispute be referred to mediation, to be conducted by a person agreed between the parties. If the parties cannot agree on a mediator within 20 Business Days after a request for mediation under this clause 10.1.1(d), either party may ask the chair of LEADR & IAMA ACN 008 651 232 or the chair's nominee to appoint a mediator.

10.1.2 Despite the reference of a dispute or issue to mediation under clause 10.1.1(d), the parties must continue to perform their obligations under this Agreement.

- 10.1.3 Any issue arising from the operation of clause 4 of this Agreement will be determined as follows:
- (a) the party claiming that there is an issue will send to the other party a notice setting out the nature of the issue;
 - (b) the Department Representative and the Guild Representative will then try to resolve the issue by direct negotiation;
 - (c) if the dispute is not so resolved either party may immediately request the dispute to be referred to the Tribunal for mediation, and if mediation fails, resolution; and
 - (d) if the parties resolve the dispute they shall, if required, present the agreement reached between them to the Tribunal for an appropriate determination.
- 10.1.4 Each party will bear its own costs arising from the process set out in this clause 10.1.

10.2 Consultation

Where, during the Term, the Australian Government has made a decision as part of a health-related budget initiative that has a significant and sustained impact on the viability of community pharmacy, the Commonwealth will consult with the Guild about that impact.

10.3 Variation

This Agreement may only be varied in writing, signed by the Guild and the Minister, or a delegate of the Minister.

10.4 Arrangements at the end of this Agreement

The parties will use their best endeavours to ensure that negotiations for any new community pharmacy agreement to apply after the expiry of this Agreement will commence 12 months prior to the expiry of this Agreement, and conclude by 31 March 2020.

10.5 Entire agreement

This Agreement constitutes the entire agreement of the parties about its subject matter and supersedes all previous agreements.

10.6 Words and headings

In this Agreement, unless expressed to the contrary:

- 10.6.1 words denoting the singular include the plural and vice versa;
- 10.6.2 the word 'includes' in any form is not a word of limitation;
- 10.6.3 where a word or phrase is defined, another part of speech or grammatical form of that word or phrase has a corresponding meaning;
- 10.6.4 headings and sub-headings are for ease of reference only and do not affect the interpretation of this Agreement; and

- 10.6.5 no rule of construction applies to the disadvantage of the party preparing this Agreement on the basis that it prepared or put forward this Agreement or any part of it.

10.7 Specific references

In this Agreement, unless expressed to the contrary, a reference to:

- 10.7.1 a section is a reference to a section of the Act;
- 10.7.2 any legislation (including subordinate legislation) is to that legislation as amended, re-enacted or replaced and includes any subordinate legislation issued under it;
- 10.7.3 any document (such as a deed, agreement or other document) is to that document (or, if required by the context, to a part of it) as amended, novated, substituted or supplemented at any time;
- 10.7.4 writing includes writing in digital form;
- 10.7.5 'this Agreement' is to this Agreement as amended from time to time;
- 10.7.6 'A\$', '\$', 'AUD', 'dollars' or 'cents' is a reference to Australian units of currency;
- 10.7.7 a clause, schedule, table or attachment is a reference to a clause, schedule, table or attachment in or to this Agreement;
- 10.7.8 to a 'person' includes an individual, a firm, a body corporate, a partnership, a joint venture, an unincorporated body or association, or any Government Agency; and
- 10.7.9 any body (**Original Body**) which no longer exists or has been reconstituted, renamed, replaced or whose powers or functions have been removed or transferred to another body or agency, is a reference to the body which most closely serves the purposes or objects of the Original Body.

10.8 Notices

- 10.8.1 A notice under this Agreement is only effective if it is in writing, and dealt with as follows:

- (a) if given by the Guild to the Commonwealth - addressed to:

First Assistant Secretary
Pharmaceutical Benefits Division
Department of Health

MDP 903
GPO Box 9848
CANBERRA ACT 2601,

or as otherwise notified by the Commonwealth; or

- (b) if given by the Commonwealth to the Guild - addressed to:

Executive Director
The Pharmacy Guild of Australia
Level 2, 15 National Circuit
Barton ACT 2600

PO Box 7036
Canberra Mail Centre ACT 2610,

or as otherwise notified by the Guild.

10.8.2 A notice is to be:

- (a) signed by the person giving the notice and delivered by hand;
- (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 email or facsimile transmission.

10.8.3 Communications take effect from the time they are received or taken to be received under clause 10.8.4 (whichever happens first) unless a later time is specified.

10.8.4 Communications are taken to be received:

- (a) if sent by post, three days after posting (or seven days after posting if sent from one country to another); or
- (b) if sent by facsimile, at the time shown in the transmission report as the time that the whole facsimile was sent; or
- (c) if sent by email;
 - (i) when the sender receives an automated message confirming delivery; or
 - (ii) four hours after the time sent (as recorded on the device from which the sender sent the email) unless the sender receives an automated message that the email has not been delivered,

whichever happens first.

10.8.5 A notice received, or taken to be received under clause 10.8.4 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.

Signing Page

Executed as an agreement

Dated 24 May 2015

Signed by The Honourable Sussan Ley MP,
Minister for Health and Minister for Sport
on behalf of the Commonwealth of Australia

in the presence of:

Witness

Name of witness

The Common Seal of The Pharmacy Guild of
Australia was affixed pursuant to a resolution
of its National Council in the presence of:

National President

Full name

Executive Director

Full name

Appendix A

Annual community pharmacy and wholesaler reconciliation

[Clause 5.4]

1. The parties agree that the global sum for pharmacists' and wholesalers' remuneration in respect of their core dispensing and distribution function is modelled by reference to estimated prescription volumes.
2. The Commonwealth estimates that the PBS and RPBS prescription volumes of listed brands, dispensed by community pharmacies during the Term, will be as follows:

Table 4: Estimates of PBS and RPBS prescription volumes of listed brands

Prescription type	Financial Year 2015-16	Financial Year 2016-17	Financial Year 2017-18	Financial Year 2018-19	Financial Year 2019-20
PBS and RPBS prescription volumes (m)	227.067	232.472	238.049	243.730	248.754
Prescriptions under the Maximum Co-Payment (m)	74.567	80.994	87.706	94.484	101.089
Total volume (m)	301.634	313.466	325.755	338.214	349.843

3. The parties agree that, for the purposes of the calculation of prescriptions variances under clause 5.4, prescription volume means the combined total of PBS, RPBS and general prescriptions under the Maximum Co-Payment, for items listed under section 85 of the Act that are dispensed by community pharmacies. The parties further agree to use the actual PBS and RPBS Date of Supply data published by the Commonwealth for the purposes of calculations under clause 5.4.

Appendix B

Indicative Allocations for Community Pharmacy Programmes

[Clause 6.1]

Programme name	Description of Programme¥	Year 1 of 6CPA \$m	Years 2 – 5 of 6CPA* \$m	Total \$m
Medication Adherence Programmes:	To support medication adherence programmes that are designed to improve medication compliance through the provision of community pharmacy services	65.6	123.6	189.2
Dose Administration Aids (DAA)**	To assist consumers in the community to better manage their medicines, with the objective of avoiding medication misadventure and improving medication compliance.	58.4	*	*
Staged Supply**	To support the provision of PBS medicines in instalments when requested by the prescriber (excluding the section 100 opioid dependency treatment programme). These instalments may be daily, weekly, or as otherwise agreed with the prescriber. The service is particularly targeted to patients with a mental illness, drug dependency or who are otherwise unable to manage their medicines safely.	7.2	*	*
Medication Management Programmes:	To support quality use of medicines services that are designed to reduce adverse medicine events and associated hospital admissions or medical presentations	63.4	114.9	178.3
Clinical Interventions	To identify, resolve and document drug-related issues that are identified within community pharmacy. The Programme seeks to improve patient health outcomes and improve quality use of medicines.	19.8	*	*
Home Medicines Reviews	To enhance the quality use of medicines and reduce the number of adverse medicine events, by assisting consumers to better manage and understand their medicines through a medication review conducted by an accredited pharmacist in the patient's home.	14.5	*	*
Residential Medication Management Reviews	To enhance the quality use of medicines for consumers in approved Australian Government funded aged care facilities, by assisting consumers and their carers to better manage their medicines. The programme will also support activities that are designed to improve quality use of medicines across approved Australian Government funded aged care facilities.	14.2	*	*
MedsCheck	To provide an in-pharmacy medicine review between pharmacists and consumers to enhance quality use of medicines and reduce the number of adverse medicines events.	14.9	*	*

Programme name	Description of Programme [¥]	Year 1 of 6CPA \$m	Years 2 – 5 of 6CPA* \$m	Total \$m
Aboriginal and Torres Strait Islander Specific Programmes:	To support targeted programmes and services which improve quality use of medicines and culturally-appropriate services for Aboriginal and Torres Strait Islander (ATSI) consumers	6.1	33.9	40.0
QUMAX	To enable pharmacies to work with rural and urban Aboriginal Health Services to improve the quality use of medicines by clients of those services who access PBS medicines.	2.5	*	*
S100 Support Allowance	To provide an allowance to approved pharmacies and approved hospital authorities to improve the quality use of medicines by clients of Remote Aboriginal Health Services that participate in the s100 supply arrangements.	3.3	*	*
ATSI Workforce Programme	To fund a range of initiatives designed to strengthen and support the ATSI pharmacy workforce, which in turn will provide improved, culturally-appropriate pharmacy services for ATSI consumers.	0.3	*	*
Rural Support Programmes:	To support targeted programmes and services which improve access to PBS medicines and services for people living in rural and remote regions of Australia	21.2	99.1	120.3
Rural Pharmacy Workforce Programme	To fund a range of initiatives designed to strengthen and support the rural pharmacy workforce, in turn to provide increased access to quality pharmacy services for consumers residing in rural and remote regions of Australia.	6.9	*	*
Rural Pharmacy Maintenance Allowance	To support improved access to PBS medicines and pharmacy services for people in rural and remote regions of Australia, through the provision of a support allowance which recognises the additional financial burden of maintaining a pharmacy in these areas.	14.3	*	*
eHealth:	To support initiatives designed to improve outcomes through sharing of information as part of a personally-controlled electronic health record	12.7	48.3	61.0
Electronic Prescription Fee ('EPF')	To support payment of an electronic prescription fee per transaction to approved suppliers for eligible electronic prescriptions.	12.7	*	*
Other activity:	To support additional activities under this Agreement	8.3	15.9	24.2
Programme administration and audit	To support payment administration and audit activity to be undertaken to support implementation, ongoing management and any audit activity associated with programmes that are approved to continue by the Minister.	6.8	14.4	21.2
Comprehensive review of pharmacy remuneration and regulation	To support a comprehensive, independent and public review of pharmacy regulation and remuneration (including wholesaler remuneration), within the first two years of the Term.	3 million		
TOTAL		177.3	435.7	613.0

Table notes:

¥ Compliance arrangements will be used to ensure ongoing accountability.

* Funding for Community Pharmacy Programmes under this Agreement will be subject to a cost-effectiveness assessment as outlined in clause 6.1.3.

** Based on evidence already collected and available, the likelihood of these programmes being found cost-effective and being recommended for further expansion is very high. Therefore, both parties acknowledge that up to an additional \$122 million (within the total funding limit specified in clause 6.1) may be made available for Financial Years 4 and 5, subject to cost-effectiveness assessment outcomes from the Medical Services Advisory Committee (or other health technology assessment body, as determined by the Minister) and decisions by the Minister.

