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Department of Health

Standard Form Regulation Impact Statement (RIS)

March 2016

Name of proposal: Negotiation of a New Seventh Community Pharmacy Agreement

Office of Best Practice Regulation (OBPR) ID number: TBA

Background

Half a page that briefly describes the context of the proposal. Someone with no understanding of the subject should be able to read this and understand the context.

Community Pharmacy Agreements (CPA), as a five-year agreement between the Commonwealth and the Pharmacy Guild of Australia (Guild), have been a long-standing agreed mechanism supporting patient access to Pharmaceutical Benefits Scheme (PBS) medicines and associated professional pharmacy services through community pharmacies across Australia.

Central to each successive CPA has been a formal agreement between the Commonwealth and the Guild on the Commonwealth Price, being the overall price paid to PBS approved pharmacists for the supply and dispensing of PBS medicines to patients. CPAs have continued to be negotiated with the Guild as a representative of the majority of approved pharmacists, as recognised under Section 98BAA(1) of the *National Health Act 1953 (Cth)*.

CPAs have evolved over successive iterations to additionally include undertakings in relation to wholesale markup and distribution of PBS medicines supplied to approved pharmacists, and a package of funded professional pharmacy programs delivered through community pharmacies. In making successive CPAs, both parties have continued to recognise broader policy intentions and common interests in:

- promoting the sustainability, efficiency and cost-effectiveness of the PBS;
- ensuring that community resources are appropriately directed across the health system; and
- supporting the sustainability of an accessible network of community pharmacies across Australia.

The Sixth Community Pharmacy Agreement (6CPA), which commenced on 1 July 2015, expires on 30 June 2020.

Problem Definition

This section should be no more than one page that clearly identifies between two to eight problems to business, community organisations or individuals. Each problem should be separately identified. A clear problem definition leads to a strong RIS.

This proposal seeks to establish the parameters under which the Seventh Community Pharmacy Agreement (7CPA) will be negotiated, to commence from 1 July 2020. A 7CPA would maintain arrangements for: pharmacist remuneration for the supply and dispensing of PBS medicines; wholesaler mark-ups and finding arrangements supporting the timely supply of PBS medicines to community pharmacies across Australia; and funding for the delivery of a range of professional pharmacy programs in medication management and related services, supporting the safe and effective use of medicines within the community.

It is expected that under the proposed 7CPA (as outlined in the Submission), patients would benefit by:

- continued access to cheaper medicines through continuation of an optional \$1 discount on PBS patient copayments, by which patients have benefited from approximately \$55 million in savings each year;



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- continued access to a range of ongoing professional pharmacy services, including dose administration aids and medication management services for older Australians;
- improved access to medicines for Aboriginal and Torres Strait Islander people (enabling Aboriginal and Torres Strait Islander people to utilise PBS Closing the Gap arrangements, without being limited by their location or whether or not they have a chronic disease); and
- improved access to medicines information including on the cost of medicines (with patient out-of-pocket expenses minimized and transparent).

Objective of Government Action

This section should be no more than half a page and using separate dot points describe the government's objective.

In establishing the 7CPA Government seeks to continue activities currently supported under the 6CPA, including: pharmacy remuneration; wholesaler mark-up and supply funding arrangements; and funding for professional pharmacy programs. Through its proposed approach Government seeks to realise the following objectives from the 7CPA:

1. maintaining the optional \$1 discount on PBS patient copayments;
2. ceasing the Premium Free Dispensing Incentive fee, recognising that generic brands of medicines are now widely used in the industry and community, and redirecting the funding [REDACTED] into pharmacy dispensing remuneration and pharmacy programs, at nil net cost to Government;
3. re-prioritising and continuing existing pharmacy programs at a level that will be contingent on the agreed overall funding envelope for all components of the 7CPA;
4. including the Pharmaceutical Society of Australia as an additional signatory to the 7CPA, ensuring a greater level of consultation on the future development and delivery of professional pharmacy services funded under the agreement;
5. increasing and restructuring the remuneration for wholesaling and distributing PBS medicines and the Community Service Obligation (CSO) arrangement for wholesalers, at an additional cost of up to [REDACTED] to Government; and
6. supporting in-principle the administration of vaccines included on the National Immunisation Program Schedule by trained registered pharmacists, where clinically appropriate and authorised by legislation.

Policy Options

Describe three or more options to address the problems described. One option must be maintaining the status quo which is the base case. (A RIS needs to have at least three options unless the agency certifies in the RIS that the policy problem and circumstances are such that fewer than three options are feasible for consideration.)

Options available to continue the activities currently supported under the 6CPA are:

1. Establishment of a new five-year 7CPA, to commence from 1 July 2020; or
2. In the absence of an agreement between the Commonwealth and the Guild, the Pharmaceutical Benefits Remuneration Tribunal (PBRT) will determine the Commonwealth Price, with separate arrangements to be established (similar to those operating under the 6CPA), for funding of wholesaler mark-up and supply, and professional pharmacy programs.

Option 1 – Establishment of a New 7CPA

Option Overview

Provide an overview of the proposed option



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This *preferred* option is for the establishment of a new 7CPA which will continue activities as currently provided under the 6CPA, with benefits for consumers, Government and the pharmacy sector.

In seeking to achieve a negotiated 7CPA with the Guild and other key stakeholders this option would realise each of the objectives outlined above.

Specifically, this option would bring changes to current arrangements under the 6CPA with respect to:

- *Pharmacy remuneration structures and levels* – to provide rebased values and growth rates to support ongoing remuneration over the course of the five-year 7CPA.
- *Wholesaler remuneration arrangements* – to make adjustments to wholesaler mark-up arrangements, including introduction of a minimum wholesaler mark-up floor per PBS item supplied, and providing additional investment into the Community Service Obligation (CSO) Funding Pool; and
- *Pharmacy programs* – to deliver an ongoing investment in a range of pharmacy services aimed at supporting the quality use of medicines, including the safe and effective use of medicines.

Impacted Parties

Describe the potentially impacted parties such as business, community organisations or individuals.

Parties benefiting from these arrangements include:

- community pharmacies in relation to remuneration for supply of PBS medicines;
- consumers in relation to maintenance of the cost of PBS medicines from approved pharmacies.
- pharmaceutical wholesalers, including those participating in the CSO Funding Pool arrangements;
- pharmacy owners and pharmacists engaged in the delivery of pharmacy programs, residents and staff of Residential Aged Care Facilities and eligible members of the public.

Impact Analysis

Describe the impact of each option on each of the impacted parties identified above, impacts could be direct or indirect. The Regulatory Burden Estimate (RBE) Table at Appendix 1 is required to be included in this section if there are regulatory costs associated with this option. Provide evidence to support costing information such as referencing and sources.

Community pharmacies will be most directly affected by any changes to pharmacy remuneration. The specific parameters for the proposed changes to pharmacy remuneration have been negotiated with the Guild as specified in *the National Health Act 1953 (Cth)* as the representative of the community pharmacy sector.

Consumers will continue to be able to access medicines and pharmacy services. Consumers will also be affected by changes to pharmacy remuneration in relation to potential increases to medicines priced below the PBS general patient copayment for there is no pharmaceutical benefit paid by the Commonwealth. However, as the overall increase in pharmacy remuneration would be broadly consistent with indexation in the long-term, the impact on consumers will be marginal, being most notable at commencement of the 7CPA.

All pharmaceutical wholesalers will benefit from an increase to the wholesale mark-up. The six wholesalers currently participating in the CSO Funding Pool arrangements will further benefit from an increase to the CSO Funding Pool.

Some pharmaceutical manufacturers which have medicines with Special Pricing Arrangements or with a Brand Price Premium may also be impacted by increased costs due to the way these arrangements currently operate.

Changes to pharmacy program will impact pharmacy owners and pharmacists engaged in their delivery, residents and staff of Residential Aged Care Facilities and eligible members of the public. Continuation of the 6CPA pharmacy programs in their current form from 1 July



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2020 for the first year of the 7CPA will provide for implementation and transition activities for redesigned programs to be phased in from year two of the 7CPA. This approach will limit impacts on providers and community from program changes.

Option 2 – Arrangements in the Absence of a CPA

Option Overview

This option involves letting the 6CPA lapse, in which case existing pharmacy remuneration would continue until the PBRT holds an inquiry to independently determine the Commonwealth Price (without indexation).

Under this option separate funding arrangements would be pursued with relevant stakeholders for:

- adjustments to wholesaler mark-up arrangements, including introduction of a minimum wholesaler mark-up floor per PBS item supplied, and providing additional investment into the Community Service Obligation (CSO) Funding Pool; and
- ongoing investment in a range of pharmacy services aimed at supporting the safe and effective use of medicines.

Impacted Parties

Parties benefiting from these arrangements would include

- Community pharmacies in relation to remuneration for supply of PBS medicines;
- Consumers in relation to maintenance of the cost of PBS medicines from approved pharmacies.
- All pharmaceutical wholesalers, including those participating in the CSO Funding Pool arrangements;
- Pharmacy owners and pharmacists engaged in the delivery of pharmacy programs, residents and staff of Residential Aged Care Facilities and eligible members of the public.

Impact Analysis

With the exception of community pharmacies in relation to supply of PBS medicines, impacts to stakeholders from this option would not be expected to differ from those from *Option 1 – Establishment of a New 7CPA*.

Consultation

In this section provide a description about the type of consultation that was undertaken and then provide a description of the results or outcome of the consultation.

Nature of consultation

Provide an overview of the consultation that was undertaken.

More than 80 consultation and negotiation meetings have been held to date, including two stakeholder round tables, with national pharmacy, health and consumer organisations to inform development of a 7CPA that will support improved affordability of and increased access to medicines and effective pharmacy services.

Impacted parties

Provide an overview of the results and outcomes of the consultation.

Government has rigorously negotiated with the Guild for over 10 months, consistent with the [REDACTED] agreed negotiation strategy, toward achieving the proposed objectives for a 7CPA described above. The proposed position for a 7CPA now represents the best compromise



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achievable within the available funding envelope without impacting the sustainability of the community pharmacy sector.



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Preferred Option

Clearly state the preferred option and why the conclusion must be supported by the preceding analysis.

The preferred option is the establishment of a new 7CPA by 30 June 2020, and which would achieve each of the objectives outlined above.

Implementation

Consider how the option will be implemented and enforced, consider practical implementation issues such as, legislative timeframes, administrative issues such as accountability, risks and mitigations, transitional arrangements and enforcement issues.



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Appendix 1

Regulatory Burden Estimate (RBE) Table

Average Annual Regulatory Costs (from business as usual)				
Change in Costs (\$m)	Business	Community Organisations	Individuals	Total change in cost
Total by Sector	\$	\$	\$	\$

Please also consider the offsets for the regulatory costs associated with the proposal. If no offset has been identified, has the Deputy Secretary or delegate warranted that the net regulatory target will be met by the end of the relevant reporting period?

Are all new costs offset?

- Yes, costs are offset, *please provide information below*
- Deregulatory, no offsets required

Total (Change in costs - cost offset) (\$ million): \$

What are the offsets for increases in regulatory costs associated with this proposal?