

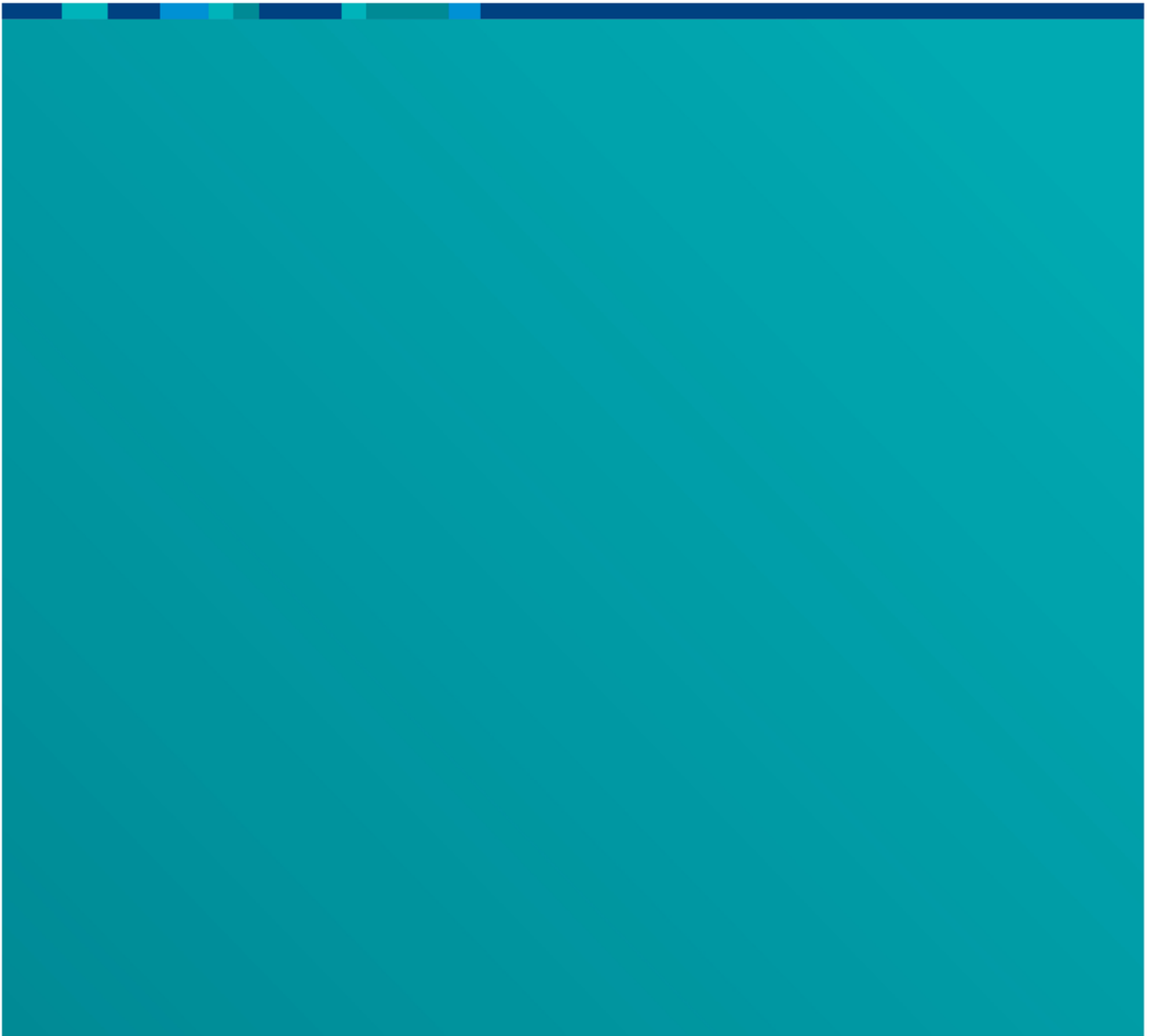


Australian Government
Department of Health and Aged Care

IMPACT ANALYSIS

NEGOTIATION OF NEW COMMUNITY PHARMACY AGREEMENT

OFFICE OF IMPACT ANALYSIS ID: OIA23-05019



Contents

Executive Summary	4
Background.....	9
1.1 Community pharmacy.....	9
1.2 The PBS.....	9
1.3 The History of CPAs	11
1.4 Pharmacy regulation outside of the CPA	16
1.6 60 Day dispensing.....	17
1.7 The Review of Pharmacy Remuneration and Regulation.....	18
Impact Analysis.....	21
1. What is the problem this proposal will solve?.....	21
Commonwealth price	21
Maximising equitable and affordable access to medicines and pharmacy services	23
Quality use of medicines and medicines safety.....	34
Collaborative, innovative and sustainable pharmacy industry.....	38
2. Why is government action needed?	40
Person-centred	42
Equity, sustainability and access for consumers	43
Equity, sustainability and access for businesses.....	43
Accountability and Transparency	45
Innovation and Continuous Improvement	45
Potential Barriers to the Government Meeting its Objectives	45
3. What policy options are you considering?	47
Option 1: Continuation of the 7CPA until 30 June 2025 and no new Community Pharmacy Agreement following its expiry (Status Quo).....	47
Option 2: Establish an 8CPA that includes all existing pharmacy programs	50
Option 3: Establish an 8CPA for dispensing remuneration and only pharmacy programs delivered directly through community pharmacies	52
4. What is the likely net benefit of each option?.....	55
5. Who will you consult about these options and how will you consult them?	66
Summary of feedback from consultations.....	68
Ongoing consultations	70
6. What is the best option from those you have considered and how will it be implemented?	71
Preferred option	71
Implementation	73
Communications.....	74
7. How will you evaluate the chosen option against the success metrics?	75

Evaluation questions	75
Evaluation framework for CPPs	75
Monitoring stakeholder impacts	79
APPENDICES.....	81
1. Abbreviations	81
2. Glossary	83
3. Jurisdictional ownership rules	86
4. Comparative Commonwealth price under previous CPAs	88
5. Community Pharmacy Programs in the 7CPA	92
6. Method and assumptions made in calculating the Regulatory Burden Estimates.....	94

Executive Summary

This Impact Analysis (IA) has been prepared to support Government consideration of a new Community Pharmacy Agreement (CPA) relating to payments for the supply of subsidised Pharmaceutical Benefits Scheme (PBS) medicines to Australians, and related matters, as required under the Australian Government's Policy Impact Analysis Framework. This IA addresses all seven questions of the Australian Government Guide to Policy Impact Analysis.

All options considered for payments and policy related to the supply of subsidised PBS medicines to Australians will be considered in terms of their ability to support achieving the outcomes under the high-level framework established by the National Medicines Policy¹ (NMP). The NMP promotes the quality use of medicines and medicines safety to meet the current and future health needs of the community. It sets out the responsibilities of all partners involved in supplying medicines to achieve the best health, social and economic outcomes for all Australians. It acknowledges the fundamental role of consumers in achieving the policy aim by placing the individual at the centre, and by responding to the needs of Australia's diverse population. The Department of Health and Aged Care (the Department) has undertaken extensive consultation with multiple consumer organisations about issues that may be the subject of a new CPA.

The primary intent of entering into a CPA to remunerate pharmacists for the dispensing of medicines, and potentially medicines-related services, is to ensure all Australians have optimised access to timely, safe and affordable medicines. Community pharmacies, which are private sector (retail) pharmacies, are a critical component of the Australian health system, providing consumer access to PBS subsidised medicines and related services across Australia².

All areas of the pharmacy sector, including wholesalers, compounding pharmacies, hospital pharmacies, and other entities, are affected by the Commonwealth price of PBS subsidised medicines agreed through the CPA. Since 1990 the Commonwealth has entered into seven CPAs with the pharmacy sector, usually each operating for a term of 5 years. Initially the CPAs were restricted to establishing the parameters for the Commonwealth price paid to pharmacies for dispensing PBS medicines, as set out in the *National Health Act 1953* (the Act), and were agreements between the Commonwealth of Australia and the Pharmacy Guild of Australia (the Guild).

CPAs have evolved over time to include a broader range of services to help achieve health outcomes for Australians, including public funding for medicine adherence programs, medicine management programs and specific programs to support Aboriginal and Torres Strait Islander peoples.

Section 98BAA of the Act requires the Pharmaceutical Benefits Remuneration Tribunal (PBRT) to give effect to the terms of any pricing agreement between the Minister for Health and Aged Care (the Minister) and the Guild, or other organisation representing a majority of

¹ <https://www.health.gov.au/resources/publications/national-medicines-policy?language=en>

² <https://www.aihw.gov.au/reports/australias-health/health-system-overview>

community pharmacy owners approved to dispense PBS medicines. The CPA has operated as the pricing agreement which gives effect to that section of the Act.

The Guild³ is the national employer organisation, which represents Australia's community pharmacy owners. It seeks to serve the interests of its members and to support community pharmacy in its role of delivering quality health outcomes for all Australians. Data supplied to the Department by the Guild show that as of 30 June 2023 it had 4,154 member pharmacies. This is equivalent to approximately 70% of pharmacies and demonstrates that the Guild continues to represent the majority of approved pharmacists. To become a full member of the Guild, pharmacists must own or partially own a pharmacy. Associate membership status is available to pharmacists who do not own a pharmacy.

The Hon Mark Butler MP, Minister for Health and Aged Care announced the Government's decision to enter into early negotiations for an 8CPA on 7 August 2023.⁴ In his announcement the Minister also stated that consultations would include patient groups, medicines wholesalers and distributors, and others who have a stake in the growth and development of pharmacy services that benefit all Australians.

Preparation of this IA and stakeholder consultation commenced following the Minister's announcement. Drawing on stakeholder input, previous reviews and other evidence, the Department developed the proposed options outlined in this IA to respond to the identified problems. In October 2023, an early assessment IA supported Government's decision in relation to a high-level negotiation framework for an 8CPA. In November 2023 a First Pass IA was prepared to support Government's decision regarding the detailed negotiating parameters for a potential new community. This final version of the IA is intended to inform Government's consideration of the potential establishment of an 8CPA.

This proposal considers three options for the future remuneration for delivery of PBS medicines to Australians:

- Option 1: Continuation of the 7CPA until 30 June 2025 and no new CPA following its expiry, unless one can be negotiated before this date (Status Quo)
- Option 2: Establish an 8CPA that includes all existing pharmacy programs
- Option 3: Establish an 8CPA for dispensing remuneration and only pharmacy programs delivered directly through community pharmacies

Option 1, to not negotiate a new CPA, would not be supported by the community pharmacy sector, which is seeking certain (guaranteed) increased remuneration from the Government for dispensing medicines prior to the 7CPA expiry on 30 June 2025.

Under this option, ongoing negotiations could produce a new CPA to operate when the current 7CPA expires on 30 June 2025. If no further agreement is able to be negotiated by 30 June 2025, then after that date remuneration for dispensing would be set by the

³ <https://www.guild.org.au/about-us>

⁴ <https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/negotiations-for-an-eighth-community-pharmacy-agreement?language=en>

independent PBRT following a public inquiry which would occur after the conclusion of the term of the 7CPA.

The PBRT operates independently of the Department. The Department is unable to predict whether remuneration to pharmacies for dispensing prescriptions under the PBS might increase, decrease or remain the same. This IA document has not sought to model the possible regulatory or budgetary impact of different possible scenarios of remuneration which might be agreed by the PBRT in recognition of the independence of that entity and so as to not compromise or influence their inquiries, deliberations or negotiations.

In 1989 the PBRT concluded an enquiry into the efficient cost of dispensing medicines by examining surveys into pharmacies' dispensing costs, the PBRT concluded that pharmacy owners were being over-remunerated for dispensing PBS medicines. The PBRT decided to change pharmacy remuneration by abolishing the 25% mark-up then applying to PBS medicines, and reducing the dispensing fee by 23%. Following this decision pharmacists took the exceptional action of holding public rallies with some owners closing their pharmacies.⁵ The then Minister for Aged, Family and Health Services subsequently negotiated directly with the Guild, and on 6 December 1990, entered into what was to become the first CPA to establish set values for dispensing remuneration.

The PBRT would look at all aspects that make up the cost of efficient dispensing. Community Pharmacy Programs (CPPs) which are covered under the 7CPA, would continue until such time as the Government makes further policy decisions to change or reform the programs, for instance to enable implementation of Quality and Evaluation Frameworks developed in consultation with stakeholders.

In addition to pharmacies, wholesalers would be impacted by the expiry of current arrangements without certainty over future wholesaler mark-ups included in the Commonwealth price, of funding provided through the Community Service Obligation (CSO), which also forms part of the 7CPA.

Option 2 seeks to broadly maintain the individual components of the existing CPA, but the Government would negotiate with the Guild on the level of remuneration for each component. This option presents little scope for applying any real and meaningful reforms to the agreement and programs that currently sit under the 7CPA, but would provide assurance of remuneration for dispensing PBS medicines and continuation of existing programs.

Option 3 would enable the Government to work with a wider range of stakeholders, including but not limited to the Guild and the PSA, to develop and implement a comprehensive Quality and Evaluation Framework for pharmacy programs, by reducing the scope of the next CPA to only those elements required under section 98BAA of the Act and to CPPs that are delivered directly through community pharmacies. Programs outside of the CPA could be altered or replaced with new initiatives after stakeholder consultation without

⁵ Jackson, J.K., Scahill, S.L., Mintrom, M. *et al.* An evaluation of the Australian Community Pharmacy Agreement from a public policy perspective: industry policy cloaked as health policy?. *J of Pharm Policy and Pract* **16**, 71 (2023). <https://doi.org/10.1186/s40545-023-00571-y>

being tied to CPA timeframes or commitments not to make changes. Those programs remaining in the CPA would be subject to establishment of individual evaluation frameworks.

Consultation with a wide range of stakeholders including pharmacy owners and pharmacist organisations, rural pharmacy organisations, wholesalers, consumer organisations and medical professional organisations has been undertaken. The aim of these consultations was to gain as wide as possible a reflection on what stakeholders want included in any new agreement and what can be ceased or considered outside of a possible 8CPA. Overall there was strong support to reform the structure and function of any new agreement to focus more on remuneration for dispensing PBS medicines and for other aspects such as CPP to be funded and negotiated outside of the agreement.

Alongside this was strong support for reform within the CPP space to embed evaluation of the clinical benefit and value for money into each program. Suggestions for new programs within the pharmacy space to be funded outside of any new 8CPA were also received from numerous stakeholders. Consultations with multiple stakeholders including the Guild and PSA will continue to inform any separate agreements to be considered by Government.

Taking into consideration the stakeholder feedback the preferred option is Option 3 in that it provides the best platform in which to pursue reform to the programs currently funded through the 7CPA and consider the establishment of new appropriately targeted programs. An 8CPA agreed to through this option would be restricted to defining the structure, initial values and indexation of the components that make up the Commonwealth price and the CPPs delivered directly through community pharmacies.

Other aspects currently covered under the 7CPA, only negotiated with pharmacy owners and pharmacist groups, would move outside of the CPA and could be developed, implemented, monitored, evaluated and reformed in consultation with a wider range of interested stakeholders. This option would allow the Government to work with relevant stakeholders to develop robust evaluation frameworks for both existing and new CPPs.

A number of current programs under the CPA lack the data collection and reporting capability to inform meaningful evaluation of their effectiveness. This limitation would be addressed under this option both for programs under the CPA and those outside of it. This would bring these programs into line with best government practice where regular reviews of government funded programs ensure they demonstrate the effective and efficient use of government resources under the *Public Governance, Performance and Accountability Act 2013* (PGPA Act),⁶ and the Government is not restricted by negotiated commitments in its ability to evaluate and improve the operation of publicly funded programs, with the interests of the Australian community at the centre.

In developing an agreement on how to fund the future delivery of subsidised PBS medicines to Australians, the Department will also seek to develop metrics and evaluation plans to ensure that the final policy position delivers the objectives of the policy. The Department

⁶ <https://www.finance.gov.au/government/setting-commonwealth-entity/governance-compliance>

will aim to measure whether the implementation of the policy is maximising equitable and affordable access to PBS medicines as intended and controlling spending on PBS dispensing remuneration. Frameworks will also be developed to evaluate whether CPPs are providing clinical benefit to consumers, provide value for money and enhance the other work of the Department in maximising the quality use of medicines.

Background

1.1 Community pharmacy

Community pharmacies are among the most accessible of health care destinations in Australia, with 97 per cent of people in capital cities and 66 per cent of people in the rest of the country living within 2.5 kilometres of their nearest pharmacy.⁷ On average, Australians visit a pharmacy 18 times a year,⁸ with pharmacies dispensing more than 200 million PBS prescriptions each year.⁹

Community pharmacy and pharmacists therefore play a key role in primary health care in Australia providing access to PBS medicines and related professional pharmacy services to the community. For most Australians, a community pharmacy is their preferred access point for a range of medicines and health care products, such as:

- prescription medicines, including those supplied through the PBS
- over-the-counter medicines, including those only available when supplied by a pharmacist, and
- non-scheduled medicines¹⁰, healthcare, and other products, such as cosmetics, that are also available from retail outlets, including supermarkets.

1.2 The PBS

The PBS is a national, government-funded scheme that, as at November 2023, subsidises the cost of 932 different medicines available in 2,470 forms, 5,311 items and marketed as 5,282 brands across a wide range of diseases for all Australians to help them afford effective, safe and cost effective treatments. Medicines available under the PBS are subsidised for conditions for which evidence supports their effective, safe and cost effective use.¹¹

The PBS is a key program supporting delivery of the Government's NMP¹² which aims to "focus on achieving positive health results that matter to people and their communities and make sure all Australians have timely, safe and reliable access to effective, high-quality medicines." The PBS is available to all Australian residents who hold a current Medicare card. Overseas visitors from countries with which Australia has a Reciprocal Health Care Agreement also have access.

⁷ The Pharmacy Guild of Australia 2020

⁸ Pearson, D., De Lure, R. (2021) NAB Pharmacy Survey 2021. NAB. <https://business.nab.com.au/nab-australian-pharmacy-survey-2021-48091/>

⁹ <https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions-report-1-july-2021-to-30-june-2022>

¹⁰ Non-scheduled medicines are medications that are not restricted to access only from a chemist, vitamins, herbal remedies and some painkillers such as aspirin and paracetamol in low dose formulations.

¹¹ https://www.health.gov.au/sites/default/files/documents/2019/10/department-of-health-annual-report-2018-19_0.pdf

¹² <https://www.health.gov.au/nationalmedicinespolicy>

The PBS and the functions of the Pharmaceutical Benefits Advisory Committee (PBAC) are established by the Act. The PBAC is a statutorily independent expert advisory committee with the primary role of recommending to the Minister, which medicines and medicinal preparations should be subsidised under the PBS and which vaccines should be subsidised under the National Immunisation Program. In making a recommendation PBAC must take into account the safety, cost and clinical effectiveness of the medicine when compared with other treatments for the same condition. Under the PBS, the Australian Government subsidises the cost of medicines to treat most medical conditions.

Before a medicine can be listed on the PBS, it must first be approved for use in Australia by the Therapeutic Goods Administration (TGA). The TGA is responsible for ensuring that the medicine meets the required standards of quality, safety and efficacy for the intended use. A medicine that is assessed by the TGA as meeting these requirements is listed on the Australian Register of Therapeutic Goods (ARTG) and can be marketed in Australia. However, the medicine will not attract an Australian Government subsidy unless it is also listed on the PBS, following an assessment by the PBAC of its comparative safety, effectiveness and cost effectiveness (that is, compared with other treatments available to treat a specific condition). Without the PBS subsidy, patients may have to pay the full cost of the medicine.

The operation and function of the PBS is outside the scope of this proposal which considers the options to give effect to the Commonwealth price for the dispensing of PBS medicines and certain other pharmacy services, such as CPPs which may come under the CPA. This is achieved either as agreed between the Commonwealth and the Guild (then ratified by the PBRT), or following a decision of the PBRT if there is no agreement in place, as required under section 98BAA of the Act. These are the only two legislated options for determining the payments approved pharmacists receive for dispensing PBS medicines.

Most PBS medicines are dispensed by community pharmacies and used by patients at home. These are known as 'General Schedule' or 'section 85' medicines because section 85 of the Act establishes the ability for the Minister to list medicines on the PBS and for the Commonwealth to supply these as a pharmaceutical benefit.

In addition to medicines and medicinal preparations available under general (section 85) PBS arrangements, a number of medicines also available as pharmaceutical benefits are distributed under alternative arrangements. Section 100 of the Act provides for alternative ways of providing a medicine when the usual supply through community pharmacies may be unsuitable. There are several programs funded under this provision including: the Highly Specialised Drugs Program; the Efficient Funding of Chemotherapy Program; the Botulinum Toxin Program; the Human Growth Hormone Program; and the IVF program.

1.3 The History of CPAs

The Government has reimbursed approved pharmacists, as the owners of community pharmacies, for dispensing PBS medicines to the public since the PBS was initially established in 1948.¹³

From 1953 to 1976, the Minister for Health was empowered under section 99 of the Act to determine pharmacy remuneration for the dispensing of PBS medicines. In 1980, the Australian Parliament's Joint Committee of Public Accounts recommended the establishment of an independent tribunal to determine pharmacy remuneration for PBS dispensing.¹⁴ In 1981, the PBRT was established under section 98A of the Act and operates independently of Government to determine the Commonwealth price¹⁵ paid to approved pharmacists for dispensing PBS subsidised medicines. An approved pharmacist in this sense is a pharmacist who has sought and received from the Secretary of the Department, or their delegate, approval to supply pharmaceutical benefits at particular premises under section 90 of the Act. Other suppliers who can also claim PBS benefits controlled by the Commonwealth price include Friendly Society pharmacies and approved hospitals.

First Community Pharmacy Agreement

In 1989, after examining surveys into pharmacies' dispensing costs, the PBRT concluded that pharmacy owners were being over-remunerated for dispensing PBS medicines.¹⁶ The PBRT decided to change pharmacy remuneration by abolishing the 25% mark-up then applying to PBS medicines, and reducing the dispensing fee by 23%. Pharmacists and the Guild opposed this decision and the then Minister for Aged, Family and Health Services subsequently negotiated directly with the Guild entering into what was to become the first CPA on 6 December 1990.¹⁷ Also, at this time, the Act was amended to require that the PBRT give effect to the terms of any pricing agreement between the Minister for Health and the Guild, or another pharmacists' organisation that represents a majority of approved pharmacists.

Specifically, section 98BAA(1) of the Act provides that:

'...where the Minister (acting on the Commonwealth's behalf) and the Pharmacy Guild of Australia or another pharmacists' organisation that represents a majority of approved pharmacists have entered into an agreement in relation to the manner in which the Commonwealth price of all or any pharmaceutical benefits is to be ascertained for the purpose of payments to approved pharmacists in respect of the supply by them of pharmaceutical benefits, the Tribunal, in making a determination

¹³ C Sloane, *A History of the Pharmaceutical Benefits Scheme 1947–1992*, Australian Government Publishing Service, Canberra, 1995, pp. 52–59.

¹⁴ Joint Committee of Public Accounts, *Report 182: Pharmaceutical Benefits Scheme-Chemists' Remuneration*, Australian Government Publishing Service, Canberra, 1980, p. xiii. In this inquiry the Committee examined and reported on the reasons for a significant excess payment by the Department of Health to pharmacists in respect of their remuneration under the PBS between 1973 and 1980. The Committee also examined the concurrent excess payments made by the Department of Veterans' Affairs to pharmacists under the RPBS. The combined total of overpayments was estimated at approximately \$253 million.

¹⁵ As defined under section 84 of the *National Health Act 1953*.

¹⁶ Pharmaceutical Benefits Remuneration Tribunal, *Data Base Inquiry Final Report*, Canberra, 28 August 1989.

¹⁷ https://web.archive.org/au/awa/20220603170441mp_/https://www.pbs.gov.au/general/sixth-cpa-files/1cpa.pdf

under subsection 98B(1) while the agreement is in force, must give effect to the terms of that agreement.’

In the absence of there being such an agreement in force, the PBRT is otherwise empowered to hold an inquiry to ascertain whether the Commonwealth price of all or any pharmaceutical benefits should be varied (section 98BA (1)).

The first CPA (December 1990 – June 1995) was thus reached against a background where:

- an inquiry conducted by the PBRT had indicated that pharmacists were being remunerated considerably more than the cost of dispensing;
- existing remuneration arrangements for community pharmacy included an “economy of scale factor”¹⁸ which allowed for the remuneration per prescription to be lower the greater the number of prescriptions that a pharmacy dispensed, but also if the average prescription volumes decreased, the remuneration per prescription increased; and
- the overall pharmacy to population ratio in Australia was, at the time, considered high compared to other developed countries.

Further, at the time of the introduction of the first iteration of the Pharmacy Location Rules (Location Rules) in 1990, there was concern about the unevenness of the distribution of pharmacies. The PBRT inquiry noted that many areas had pharmacies located within 10 metres of each other, 25 % of pharmacies were within 100 metres of another pharmacy and 62 % were within one kilometre of another pharmacy.

In contrast, consumers in rural and remote areas had relatively poor access, with a significantly lower pharmacy to population ratio. Some rural and remote consumers experienced distance barriers to accessing pharmacies, which made it difficult or expensive for consumers to access medicines. This had the potential to contribute to poorer health outcomes for rural and remote Australians than for those in urban or near-urban areas.

To address these issues, the Government and the Guild agreed to set out a new remuneration framework. This, coupled with the Location Rules, led to a more rational distribution of pharmacy services, resulting in industry restructuring that would lower pharmacy numbers and encourage greater efficiency, profitability and economies of scale in individual pharmacy businesses.

In the short term, the first CPA enabled two major policy objectives to be met: winding back of what was then considered unsustainable growth in PBS remuneration, and a rationalisation and reduction in the number of relatively inefficient pharmacies via the introduction of the Location Rules.

¹⁸ The “economy of scale factor” refers to a feature of remuneration at the time, whereby dispensing remuneration reduced with increasing volume. That is, the greater the number of prescriptions that a pharmacy dispensed, the lower the average payment per medicine dispensed.

Second Community Pharmacy Agreement

The second CPA (April 1995 – June 2000)¹⁹ sought to consolidate the remuneration structure and efficiency gains of the first CPA.

This Second CPA recognised the role of the newly formed Australian Community Pharmacy Authority (ACPA), empowered under the Act to make recommendations on the approval of pharmacists for the supply of pharmaceutical benefits from specific premises, so maintaining restrictions on the locations of PBS approved pharmacies.

The Agreement also provided for a number of consumer access-linked allowances, including a Remote Pharmacy Allowance and Isolated Pharmacy Allowance, and a fee for service to accredited pharmacists conducting medication reviews for residents of aged care facilities.

Third Community Pharmacy Agreement

The Third CPA (July 2000 – June 2005)²⁰ reduced the emphasis on prescription-based remuneration arrangements and included risk sharing provisions in response to the likelihood of prescription volumes and/or average prescription income exceeding or falling short of agreed estimates.

The Location Rules were modified with relaxed requirements for both new and relocated pharmacy approvals, particularly in rural and remote areas. Enhanced financial incentives for pharmacists to relocate to, to continue working in, or to set up new businesses in rural and remote areas were also introduced.

This CPA also introduced an enhanced medication management service to extend and improve assistance to elderly patients in managing their medications as well as remuneration for the supply of Highly Specialised Drugs for patients of private hospitals.

Active management of the Third CPA was undertaken by an Agreement Management Committee comprised of membership from the Department, the Guild, and the PSA. Administration of the Location Rules continued to be managed by the ACPA.

Fourth Community Pharmacy Agreement

The Fourth CPA (December 2005 – June 2010)²¹ continued remuneration and risk share arrangements from the Third CPA and made amendments to the Location Rules in respect of relocating pharmacies in large medical centres, small shopping centres, single pharmacy towns and high growth single pharmacy urban areas.

Consultation and governance arrangements included an Agreement Consultative Committee and a separate Professional Programs and Services Advisory Committee to consider issues relating to professional pharmacy programs and services funded under the CPA. Funding for professional pharmacy programs and services totalled \$500 million under the Fourth CPA compared to \$400 million under the Third CPA.

¹⁹ https://web.archive.org/awa/20220603170440mp_/https://www.pbs.gov.au/general/sixth-cpa-files/2cpa.pdf

²⁰ https://web.archive.org/awa/20220603170438mp_/https://www.pbs.gov.au/general/sixth-cpa-files/3cpa.pdf

²¹ https://web.archive.org/awa/20220603170620mp_/https://www.pbs.gov.au/general/sixth-cpa-files/4cpa.pdf

Significantly, the Fourth CPA also introduced the CSO Funding Pool, of \$150 million per annum, for payments to eligible wholesale distributors of PBS medicines to support their timely provision of the full range of PBS medicines to pharmacies across Australia within specified service standards, including for sales of low volume PBS medicines and sales to rural and remote pharmacies.

Fifth Community Pharmacy Agreement

The Fifth CPA (July 2010 – June 2015)²² provided for \$15.4 billion over five years, comprising \$13.8 billion in pharmacy remuneration, \$663.4 million for professional pharmacy programs and related services, and \$949.5 million for continuation of CSO Funding Pool arrangements with pharmaceutical wholesalers. In addition, a commitment was also included for retention of Location Rules over the life of the CPA.

Consultation and governance arrangements under the Fifth CPA included: an Agreement Consultative Committee (ACC) as the mechanism for consultation between the parties (Commonwealth and Guild) on implementation of all aspects of the CPA, including issues relating to pharmacist remuneration, CSO Funding Pool arrangements, Location Rules, and Programs; and a Programs Reference Group to provide advice to the Minister and the ACC, when requested, on new and continuing programs funded under the CPA.

Sixth Community Pharmacy Agreement

The Sixth CPA (6CPA) (July 2015 – June 2020)²³ was a key element of the *PBS Access and Sustainability Package*,²⁴ announced as part of the 2015-16 Budget.

The 6CPA was developed following broad consultation with a range of stakeholder groups across the pharmaceutical industry, pharmacy and pharmacists, consumers, peak groups, and other organisations. In addition, the 6CPA was developed with particular consideration towards findings and recommendations of the Australian National Audit Office's audit of the *Administration of the Fifth Community Pharmacy Agreement*²⁵ (ANAO Audit); the objective of which had been to assess the effectiveness of development and administration of the Fifth CPA and the extent to which the Fifth CPA had met its objectives.

The 6CPA provided approximately \$18.9 billion over five years, comprising: \$16.6 billion for pharmacy remuneration, \$1.26 billion for CPPs, and \$1.03 billion for CSO Funding Pool and National Diabetes Service Scheme (NDSS) product support arrangements through community pharmacy. In addition, a further \$372 million was provided in compounding fees paid directly to compounders of chemotherapy medications. The 6CPA also provided for continuation of the Location Rules over the term of the CPA. Indexation of components of the dispensing remuneration were changed from being based on wage cost index 9 to consumer price index (CPI).

²² https://web.archive.org/awa/20220603170620mp_/https://www.pbs.gov.au/general/sixth-cpa-files/5cpa.pdf

²³ https://web.archive.org/awa/20220603091322mp_/https://www.pbs.gov.au/general/pbs-access-sustainability/signed-sixth-community-pharmacy-agreement-commonwealth-and-pharmacy-guild.pdf

²⁴ www.pbs.gov.au/info/general/pbs-access-sustainability-package

²⁵ www.anao.gov.au/work/performance-audit/administration-fifth-community-pharmacy-agreement

Formal consultation arrangements under the 6CPA included an Agreement Oversight Committee (AOC), composed of equal representation from the Department and the Guild, and the Community Pharmacy Stakeholder Forum (CPSF) as an additional element allowing for communication with a broad range of stakeholders with an interest in the provision of pharmaceutical benefits and related matters and issues, including under the 6CPA.

In light of the ANAO Audit's criticism of aspects of the negotiation and administration of the Fifth CPA, the 6CPA also provided for an independent Review of Pharmacy Remuneration and Regulation, to be conducted within the first two years of the CPA.

Amended and Restated Sixth Community Pharmacy Agreement

The *2017 Strengthening PBS Compact* (Compact) was agreed between the Government and the Guild in May 2017 in response to an identified shortfall in the volume of dispensed PBS medicines against forecasts in the first year of the 6CPA. The Compact recognised the Government's commitment to ensuring the implementation of obligations under the 6CPA and secured the support of community pharmacy in making further PBS reforms.

This gave rise to the Amended and Restated Sixth Community Pharmacy Agreement (6CPA),²⁶ agreed between the Commonwealth and the Guild, which came into effect from 1 July 2017.

The Amended and Restated 6CPA provided an additional \$225 million in pharmacy remuneration through an adjustment to per-script remuneration applied over the remaining three years of the CPA. An additional investment of \$600 million was also made for new and expanded CPPs through the release of funding held in the Contingency Reserve, thus committing Government to delivering the full \$1.26 billion allocated to programs funded under the 6CPA.

Further, the Amended and Restated 6CPA provided a commitment by Government to the continuation of Location Rules beyond the term of the 6CPA through an amendment to the relevant sections of the Act to remove the sunset clause which would have otherwise seen the Location Rules cease upon expiry of the 6CPA (30 June 2020).²⁷

Seventh Community Pharmacy Agreement

The Seventh CPA (7CPA) (July 2020 – June 2025)²⁸ was developed to continue the work undertaken under the 6CPA and through consultation with multiple stakeholders similar to those in the 6CPA to expand the agreement's benefits to the community. The 7CPA was the first agreement with the community pharmacy sector to include the PSA as a co-signatory alongside the Commonwealth and the Guild for part of the CPA. PSA²⁹ is the peak national

²⁶ https://web.archive.org/awa/20220603091317mp_/https://www.pbs.gov.au/general/sixth-cpa-files/sixth-community-pharmacy-agreement-amended-06-2017.pdf

²⁷ The *National Health Amendment (Pharmaceutical Benefits-Budget and Other Measures) Bill 2017* repealed sections 90(3C) and 99Y of the *National Health Act 1953* which would have ceased the Location Rules from 30 June 2020. The Bill was passed on 13 February 2018 and gained Royal Assent on 20 February 2018.

²⁸ <https://www.health.gov.au/sites/default/files/2022-12/seventh-community-pharmacy-agreement.pdf>

²⁹ <https://www.psa.org.au/about/about-psa/>

professional pharmacy organisation representing all of Australia's 36,000 pharmacists working in all sectors and across all locations.

The 7CPA provides for approximately \$18.35 billion over five years, comprising: \$16.00 billion for pharmacy remuneration, \$1.20 billion for CPPs (which was increased to \$1.4 billion during the 7CPA), and \$1.15 billion for CSO Funding Pool and NDSS product support arrangements through community pharmacy. Indexation of components of the dispensing remuneration was fixed at 0.5% for the first two years of the agreement and then reverted back to changes in CPI for the final two years, similar to that introduced in the 6CPA.

New or revised activities within the 7CPA included:

- continued government investment in professional pharmacy programs aimed at supporting the quality use of medicines, including the safe and effective use of medicines
 - the professional pharmacy programs known as the CPP can largely be classified across the following categories: Medication Adherence programs, Medication Management programs, Rural Support programs, and Aboriginal and Torres Strait Islander specific programs
- increased government investment, program reform and increased access to PBS medicines and pharmacy services for Aboriginal and Torres Strait Islander people and older Australians
- increased support for the rural and remote pharmacy network
- greater transparency in program administration, governance and the use of public funds and a more inclusive level of representation across stakeholder groups in addition to the pharmacy sector and
- a risk-share mechanism to provide a level of certainty and predictability for the pharmacy sector for PBS dispensing remuneration and some budget certainty for the Commonwealth.

The 7CPA did not include Location Rules but contains an undertaking that the Commonwealth has no intention to change the Location Rules during the 7CPA term. This was in recognition of the sunseting arrangements for Location Rules having been removed under the National Health (Australian Community Pharmacy Authority Rules) Determination 2018 (PB 46 of 2018), made under section 99L of the Act during the term of the 6CPA.

1.4 Pharmacy regulation outside of the CPA

Community pharmacies operate in a complex regulatory environment with longstanding restrictions on location, ownership, and pricing of PBS medicines. Two significant areas of regulation relating to community pharmacy, that do not form part of the CPA are pharmacy ownership rules, which are regulated by state and territory governments under state and territory legislation, and location rules which since 2018 are legislated under Commonwealth laws. These arrangements operate independently of the CPA and are not considered in the options for this proposal.

Community pharmacy ownership rules

Each state and territory government is responsible for determining the laws relating to the establishment and operation of pharmacies, including who may own a pharmacy. As these are not areas of Commonwealth legislative authority or responsibility, they have not featured in CPAs. A summary of the existing ownership rules including who can have a pecuniary interest in a pharmacy and how many an individual or company can own or have a financial interest is included at Appendix 3.

Community pharmacy location rules

All community pharmacies (approved pharmacies) are subject to a set of location rules which govern where individual pharmacies can be established or relocated. Section 90 of the Act provides for the Secretary of the Department (or their delegate) to approve a pharmacist to supply PBS medicines at particular premises. PBS medicines are drugs or medicinal preparations for which benefits will be paid by the Commonwealth. The Secretary can generally only approve a pharmacist if the Australian Community Pharmacy Authority (the Authority) has recommended approval, and the pharmacist is permitted under the relevant State or Territory law to carry on business as a pharmacist.³⁰ The Authority makes its recommendations based on the Pharmacy Location Rules (the Rules) as outlined below.

The Rules are legislated under the *National Health (Australian Community Pharmacy Authority Rules) Determination 2018 (PB 46 of 2018)*³¹ (the Rules), made under section 99L of the Act. Prior to the passing of legislation the Rules were included in successive CPAs from the first CPA in 1990.

The Rules set out location-based criteria which must be met in order for the Authority to recommend approval of a pharmacist. The Authority cannot override the requirements of the Rules. It can only recommend that an application be approved if it is satisfied that all of the requirements of the item of the Rules, under which the application was made, have been met. Similarly, the Authority is unable to recommend that an application be approved if it is not satisfied that each of the requirements has been met.

The Rules remain consistent with the overall objective of the NPP to improve the health outcomes of all Australians through equitable access to and quality use of medicines.

1.6 60 Day dispensing

On 1 September 2023 reforms to the maximum dispensing quantities (MDQ) of certain medicines to PBS listings recommended by the PBAC (also known as 60 day prescribing or 60 day dispensing) were implemented. This change will reduce the amount people pay for medicines and mean fewer visits to the doctor and pharmacist. The implementation of 60-day dispensing is occurring over three phases in 12 months.

In the 2023-24 Budget, along with the dispensing changes, the Government committed an additional \$654.9 million over four years for CPPs. This included increasing the total budget

³⁰ [Pharmacy Location Rules Applicants Handbook 2022](#)

³¹ <https://www.legislation.gov.au/Details/F2018L01321>

for existing Programs under the 7CPA from \$1.2 billion to \$1.4 billion, as well as securing funding for these programs to continue beyond the expiry date of the 7CPA.

In addition to the further investment in existing programs the following was provided:

- \$377.3 million over four years for a nationally consistent, Commonwealth funded Opioid Dependence Treatment Program, which commenced 1 July 2023.
- \$114.1 million over four years to fund pharmacists to administer vaccines under the National Immunisation Program.
- \$79.5 million over four years to double the total annual budget for the Regional Pharmacy Maintenance Allowance, ensuring regional, rural and remote Australians have continued access to their local pharmacy.
- \$148.2 million over four years for the Regional Pharmacy Transition Allowance. This allowance will assist some pharmacies in regional, rural and remote Australia in transitioning their business arrangements to account for the new increased dispensing quantities.

The Government is committed to supporting the community pharmacy sector and through the above, all of the Government savings anticipated from the introduction of 60-Day dispensing are being reinvested back into community pharmacy, funding pharmacy services that directly benefit patients.

The 60 day dispensing measure, and the additional funding outlined above, is separate to the CPA and was the subject of a separate impact analysis³². This IA does not re-explore the previous policy decision.

1.7 The Review of Pharmacy Remuneration and Regulation

The most recent review of community pharmacies, the Review of Pharmacy Remuneration and Regulation (Pharmacy Review) was undertaken from November 2015 to September 2017 as a key component of the 6CPA. It represented the first independent, comprehensive review of the Australian community pharmacy sector in over two decades and upheld a commitment between Government and the Guild agreed to as part of the 6CPA. The Review was based on specific Terms of Reference determined by the Minister for Health following consultation with the Guild and other stakeholders.

The purpose of the Review was to provide recommendations on future remuneration, regulation (including the Location Rules) and other arrangements that apply to community pharmacies and wholesalers for the dispensing of PBS medicines and other services.

The Review was conducted by an independent three-member panel, which consulted broadly with consumers and peak industry bodies representing the pharmacy and healthcare sectors. The Panel undertook an extensive public consultation process with public forums in major population centres, and visited individual pharmacies, while commissioning research into overseas arrangements, as well as a financial analysis of the sector. The Panel developed a number of recommendations with the intention of removing

³² https://oia.pmc.gov.au/sites/default/files/posts/2023/05/Impact%20Analysis_3.pdf

unnecessary regulation and supporting both consumer access to pharmacy and government value for money, while also maintaining the viability of the sector.

The Review's final report³³ was provided to the Minister for Health in September 2017 and contained 45 recommendations framed around four key areas for reform: Minimum Pharmacy Services, Electronic Prescriptions, Pharmacy Accounting Information, and Future CPA Processes.

The Government Response to the Review³⁴ was released by the then Minister for Health in May 2018. Of the Review's 45 recommendations, the Government response:

- *accepted* four recommendations including:
 - increased access to medicines programs for Aboriginal and Torres Strait Islander people regardless of where a prescription is written or dispensed;
 - transparency regarding the funding of CPPs;
 - one electronic personal medication records system; and
 - improvements to the availability of Consumer Medicines Information.
- *accepted-in-principle* four recommendations including:
 - changes to payment administration for high-cost medicines to improve patient access through community pharmacy and address pharmacy cash flow concerns;
 - implementation of an automated PBS Safety Net recording system;
 - implementation of a system for integrated electronic prescriptions and medicines records; and
 - development of key principles that underpin the range of programs offered by community pharmacy.
- *did not support* three recommendations, namely:
 - abolition of the optional \$1 discount on the patient PBS co-payment,³⁵
 - machine dispensing of PBS medicines in communities not served by a community pharmacy; and
 - tightening the listing of generic medicines (tendering and limiting the number of generic brands of a medicine listed on the PBS).
- *noted* the remaining 34 recommendations, including those of relevance to negotiations of future CPAs.

The Review noted that successive CPAs had increased in scope beyond the requirement for an agreement on pharmacy remuneration to include funding for: professional programs and other services delivered through community pharmacy, consultant pharmacists, remuneration to wholesalers, the CSO Funding Pool, supply arrangements for products provided on the NDSS and payments to support the preparation of infusions or injections for chemotherapy provided under the PBS.

³³ [Review of Pharmacy Remuneration and Regulation Final Report](#)

³⁴ [Government Response to Review of Pharmacy Remuneration and Regulation 2018](#)

³⁵ The Discounting PBS Patient Co-Payment measure was introduced on 1 January 2016 as part of the [PBS Access and Sustainability Package](#), under the 2015-16 Budget.

The Review further noted that the Guild had been the only signatory party to each successive agreement with the Government and noted broad concern among the sector and consumers that this had translated to successive CPAs having been negotiated only between Government and a body representing the interests of pharmacy owners.

Noting that CPAs affect all community pharmacists, not just pharmacy owners, and that they also directly affect all consumers of PBS medicines, the Review suggested:

“...the value of the CPA process would be maximised if CPAs were more closely focused on the dispensing of PBS medicines, those services directly related to the dispensing function and responsibilities, and the pricing to consumers for such dispensing.”

Further, the Review suggested:

“The CPA is not the right mechanism to attempt to capture broader health programs and services or supply chain activities. These involve multiple key stakeholder groups and extend beyond the funding of PBS-related services.”

The recommendations of the Review which were accepted by government informed the 7CPA. Past findings and recommendations of reviews into the sector including those above will continue to inform the development of any potential new agreements.

Impact Analysis

1. What is the problem this proposal will solve?

The Act ensures that the Commonwealth will provide remuneration to pharmacies for the dispensing of PBS medicines, regardless of whether the Commonwealth price is outlined in a CPA (then ratified by the PBRT), or determined by the PBRT. The assumption is therefore made throughout this IA that pharmacies will continue to be remunerated by the Commonwealth for dispensing of PBS medicines.

Commonwealth price

The Government pays pharmacists to procure, supply and dispense all PBS medicines to consumers throughout Australia through the Commonwealth price. The Commonwealth price is currently agreed through the CPA and consists of:

- a Dispensing Fee, paid per prescription dispensed,
- an Administration, Handling, and Infrastructure (AHI) Fee, which is based on the cost of the drug (known as the Approved Ex-Manufacturer Price (AEMP)), and
- the Wholesale Mark-Up, which is also based on the AEMP.

In some instances there are additional components of the Commonwealth price, such as the Dangerous Drug Fee, that are paid where applicable. The Dangerous Drug Fee is for highly regulated medicines, such as opioids.

The Dispensing Fee and the AHI fee are currently indexed annually on 1 July, in line with the indexation parameters agreed through the CPA. The current values of each of the components of the Commonwealth price are included in the blue cells of Table 1 below. Table 1 also outlines the additional fees as well as the patient co-payment amounts and Safety Net thresholds as at 1 January 2024.

Table 1 PBS Fees, Patient Contributions and Safety Net Thresholds as at 1 January 2024

Dispensing Fees:	Ready-prepared	\$8.37	
	Dangerous drug fee	\$5.18	
	Extemporaneously-prepared	\$10.41	
	Allowable additional patient charge*	\$3.45	
Wholesale Mark-Up (for Ready Prepared Pharmaceutical Benefits)***	When the Ex-Manufacturer Price is up to and including \$5.50	\$0.41 per dispense	
	Where the Ex-Manufacturer Price is over \$5.50 and up to and including \$720	7.52 per cent of the Ex-Manufacturer Price per dispense	
	Where the Ex-Manufacturer Price is over \$720	\$54.14 per dispense	
Administration, Handling and Infrastructure Fee (AHI Fee)	Tier One AHI Fee	For a Listed Brand with a Price to Pharmacists for Maximum Quantity less than \$100	\$4.62 per dispense of Maximum Quantity
	Tier Two AHI Fee	For a Listed Brand with a Price to Pharmacists for Maximum Quantity from \$100 and up to and including \$2,000	Tier One AHI Fee plus 5% of the amount by which the Price to Pharmacists for Maximum Quantity exceeds \$100, per dispense of Maximum Quantity
	Tier Three AHI Fee	For a Listed Brand with a Price to Pharmacists for Maximum Quantity over \$2,000	Tier One AHI Fee and \$95 per dispense of Maximum Quantity.
Additional Fees (for Safety Net prices):	Ready-prepared	\$1.40	
	Extemporaneously-prepared	\$1.80	
Efficient Funding of Chemotherapy (EFC)**	Preparation fee	\$88.62	
	Distribution fee	\$29.15	
	Diluent fee	\$5.77	
Patient Co-payment Amounts	General	\$31.60	
	Concessional	\$7.70	
Safety Net Thresholds	General	\$1,647.90	
	Concessional	\$277.20	
Safety Net Card Issue Fee		\$12.04	

*The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment amount. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment amount for the medicine

**Public hospital pharmacies which are authorised to supply PBS-subsidised chemotherapy medicines are only eligible for the preparation fee (i.e. not the distribution or diluent fees)

***The wholesale mark-up for a Pack Quantity of a Listed Brand is calculated using the Relevant Quantity.

Source: <http://www.pbs.gov.au/info/healthpro/explanatory-notes/front/fee>

This proposal considers the available options for establishing the Commonwealth price and the parameters that will best support access to timely, safe and affordable PBS medicines for all Australians through community pharmacies, as well as arrangements for related pharmacy services, consistent with the four pillars of the NMP objectives as updated in 2022:

1. equitable, timely, safe and reliable access to medicines and pharmacy services at a cost that individuals and the community can afford
2. medicines meet the required standards of safety, quality and efficacy
3. quality use of medicines and medicines safety, and
4. collaborative, innovative and sustainable medicines industry and research sectors with the capability, capacity and expertise to respond to current and future health needs.

While strongly aligned with the first pillar, ensuring access to medicines at a cost that both individual patients and the broader community can afford, pharmacy services considered through this proposal also support the pillars of, quality use of medicines and medicines safety, and supporting a collaborative, innovative and sustainable pharmacy industry. Pillar 2 of the NMP is specific to the functions of the TGA which is responsible for the regulation of all medicines supplied in Australia and is therefore outside the scope of a CPA and is not considered further in this IA.

The IA will support Government, in making a decision to either enter into a new CPA with respect to setting the parameters for the Commonwealth price, or to allow the PBRT to hold an inquiry to ascertain whether the Commonwealth price should be varied, to have regard to the pillars and principles of the NMP.

Maximising equitable and affordable access to medicines and pharmacy services

Ensuring that the Government maximises equitable and affordable access to PBS medicines for all Australians is fundamental to the Australian health system. This currently occurs through the Australian network of community pharmacies, at least for general schedule medicines which are medicines dispensed by community pharmacies and used by patients at home.

The remuneration provided to approved community pharmacies under the CPA for the dispensing of PBS subsidised medicines is a key component of supporting timely and efficient patient access to affordable medicines, and a vital component in the Government's continued delivery of the PBS. Existing arrangements provide a level of assurance in relation to availability and costs for consumers, industry and government. A range of other

important public health services can also be delivered through pharmacies, including access to non-PBS medicines and health related services provided by pharmacists some of which are funded by the Commonwealth.

Consumers generally pay a co-payment towards the cost of PBS medicines, though many PBS medicines cost significantly more than the co-payment amount. From 1 January 2024, patients may pay up to \$31.60 for most PBS medicines, or \$7.70 if they have a concession card. The Government pays the remaining cost (with the exception of brand premiums and certain other allowable charges). Under the Closing the Gap PBS Co-Payment Program,³⁶ eligible Aboriginal and Torres Strait people who would normally pay the full co-payment pay the concessional rate, and those who would normally pay the concessional rate are not required to pay the PBS co-payment. Where the cost of a medicine, including the dispensing fee, is below the relevant patient co-payment amount the patient pays the full amount.

There are a number of different types of concession cards that provide access to PBS medicines at cheaper rates. Some cards and concessions are administered by the Commonwealth Government, while others are administered by state, territory and local governments and some private organisations.

The concession cards that are issued by the Commonwealth Government include:

- the Pensioner Concession Card (for all pensioners and certain social security allowance recipients under specific conditions)
- the Health Care Card (generally for social security recipients and low paid workers), and
- the Commonwealth Seniors Health Card (for eligible self-funded retirees who have reached the qualifying age for Age Pension).

When the Commonwealth price increases, including for example if the Government agrees to increase the dispensing fee component, then the cost to patients increases for medicines priced below the patient co-payment. If the Commonwealth price is above the relevant co-payment, then the government bears the additional cost (see example below in Table 2). Safety Net thresholds are also in place and once a patient reaches the relevant Safety Net they pay the concession co-payment for the rest of the year or for concession patients no co-payment for the rest of the year. This helps people who need more medicines to keep costs down.

³⁶ <https://www.health.gov.au/save-more-on-pbs/closing-the-gap-concession>

Table 2. Example: Rosuvastatin 10mg Tablet, 30 x 2 packs (60-day prescription) (PBS item code 13586C)

		January 2024 Price
Commonwealth Price Components	Cost of Medicine (Approved Ex-Manufacturer Price)	\$7.00
	Wholesale Mark-up	\$0.52
	Administration, Handling and Infrastructure Fee (AHI)	\$4.62
	Dispensing Fee	\$8.37
	Other fees (e.g. dangerous drug fee) when applicable	\$0
	Commonwealth Price	\$20.51
Concession Card Holder	Price to Concessional Patient - Patient Co-payment	\$7.70
	Government Cost - Commonwealth Price	\$12.81
General Patient	Price to General Patient*	\$20.51
	Government Cost - Commonwealth Price	Nil

* Price to patient for under co-payment scripts varies due to allowable discounting or additional charges. This represents the price to patient based on the legislated Commonwealth Price.

In 2022-23, PBS Government expenditure on a cash accounting basis for the supply of medicines under Section 85 and Section 100 of the Act was \$16.7 billion (excluding rebates) which is 91.4% of the total cost of PBS prescriptions. The remainder was patient contributions, which amounted to \$1.6 billion. The majority of Government expenditure in 2022-23 on PBS Section 85 and Section 100 prescriptions was directed towards concessional cardholders (\$10.5 billion, 62.6% of the total).³⁷

An Australian Bureau of Statistics survey of patient experiences over the 2022-23 financial year found that the proportion of people who delayed or did not get prescription medication when needed due to cost increased to 7.6% in 2022-23, from 5.6% in 2021-22.³⁸

The policy objective is to make medicines as affordable and accessible as possible in order to encourage consumers to use medicines prescribed to treat their health conditions. This can also be important from an economic perspective as there can be more significant health system implications if treatments are delayed or not used as intended.

Table 3 below summarises the Government Cost, patient contribution and average price for the 2005-06, 2010-11, 2015-16 and 2020-21 years. In addition, a table summarising the Commonwealth price components as outlined in successive CPAs from 2010 is provided at Appendix 4.

³⁷ <https://www.pbs.gov.au/statistics/expenditure-prescriptions/2022-2023/PBS-Expenditure-prescriptions-report-2022-23.pdf>

³⁸ <https://www.abs.gov.au/statistics/health/health-services/patient-experiences/latest-release>

Table 3. PBS Subsidised Prescriptions, Government Cost, Patient Contribution and Average Price* 2005-2021

	2005-06			2010-11			2015-16			2020-21		
Patient Category	Government Cost	Patient Payments	Ave Price	Government Cost	Patient Payments	Ave Price	Government Cost	Patient Payments	Ave. Price	Government Cost	Patient Contribution ***	Ave. Price **
Concessional Non-Safety Net	\$3,145,480,431	\$489,173,277	\$34.57	\$4,367,739,898	\$689,108,592	\$40.31	\$4,630,980,302	\$880,965,644	\$37.62	\$4,966,909,221	\$911,124,052	\$41.21
Concessional Safety Net	\$1,172,502,111	\$0	\$32.62	\$1,330,682,636	\$0	\$36.58	\$1,413,858,158	\$0	\$32.05	\$1,787,793,797	\$0	\$35.35
Total Concessional	\$4,317,982,542	\$489,173,277	\$34.07	\$5,698,422,533	\$689,108,592	\$39.47	\$6,044,838,460	\$880,965,644	\$36.33	\$6,754,703,018	\$911,124,052	\$39.68
General Non-Safety Net	\$850,095,680	\$606,897,345	\$69.65	\$1,412,781,352	\$707,968,006	\$100.83	\$1,785,357,915	\$494,124,051	\$165.53	\$2,247,741,985	\$521,358,291	\$198.28
General Safety Net	\$216,246,563	\$27,199,070	\$41.19	\$211,944,918	\$26,706,262	\$48.28	\$118,821,879	\$19,115,443	\$43.36	\$119,462,970	\$17,799,421	\$49.24
Total General	\$1,066,342,242	\$634,096,415	\$63.38	\$1,624,726,270	\$734,674,267	\$90.83	\$1,904,179,793	\$513,239,494	\$142.60	\$2,367,204,956	\$539,157,712	\$173.48
Total (excluding Drs Bag)	\$5,384,324,784	\$1,123,269,692	\$38.75	\$7,323,148,803	\$1,423,782,860	\$46.57	\$7,949,018,254	\$1,394,205,138	\$45.01	\$9,121,907,974	\$1,450,281,764	\$50.35
Doctors Bag	\$10,063,803	\$0	\$25.41	\$14,228,520	\$0	\$42.13	\$15,887,150	\$0	\$40.86	\$14,971,053	\$0	\$41.53
Total (including Drs Bag)	\$5,394,388,587	\$1,123,269,692	\$38.72	\$7,337,377,323	\$1,423,782,860	\$46.57	\$7,964,905,404	\$1,394,205,138	\$45.00	\$9,136,879,027	\$1,450,281,764	\$50.34

* Section 85only, including Drs Bag, excluding under co-payment prescriptions

** Average Price is Total Cost (cost to the patient and cost to the Government for PBS Subsidised Prescriptions) divided by PBS Subsidised Prescriptions.

*** The patient contribution does not include the effect of the \$1 PBS patient co-payment discount.

The dispensing fees determined by the Commonwealth price must balance the need to appropriately remunerate pharmacies for the services provided, in dispensing a PBS medicine and optimise access at an affordable cost, keeping in mind the importance of effectively managing public monies.

Dispensing remuneration, however, forms only part of the potential turnover achieved by pharmacy businesses and this proportion will vary from business to business. It is therefore not possible for the Department to accurately predict the viability of pharmacies based upon PBS dispensing remuneration alone. This IA does not seek to quantify the level of CPA remuneration which constitutes 'viability' for a pharmacy, either overall or in any particular set of circumstances. Nevertheless, funding under the CPA represents a key source of revenue for pharmacies and the viability of pharmacies. It is also important to note that while Commonwealth remuneration is limited to PBS medicines and the Commonwealth funded pharmacy programs and services, supporting the viability of community pharmacies also provides communities access to other medicines, goods and services provided by the pharmacy not funded by the Commonwealth.

Evidence indicates that dispensing revenue continues to form the largest portion of Community Pharmacy revenue (approximately 70%) and underpins the viability of most pharmacies.³⁹ In addition to PBS prescription medicines, certain types of medicines and other health care products are however generally available from community pharmacies, without a prescription, providing additional revenue. An Australian Institute of Health and Welfare (AIHW) study found that natural health products are the largest-selling over the counter items in pharmacies, with an estimated expenditure in 2019–20 of \$1.7 billion. Across the 15 groups of over the counter products analysed by the AIHW a total expenditure of approximately \$5 billion in 2019-20 was estimated. Medicines that require a prescription but are not eligible for subsidy under the PBS, known as private prescriptions, were estimated to have a further expenditure of \$836.0 million in the same year.⁴⁰

The Australian Taxation Office (ATO) performance benchmarks for pharmacy for 2020-21 in analysing annual turnover further show an average of total expenses in the range of 89-92%.⁴¹ It is however noted that cost structures for individual pharmacies will vary depending on size, location and business model.

Since 1990, CPAs have sought to ensure there is a fair and equitable distribution of community pharmacies within the population to enable access to PBS medicines. A goal for Government in entering into a CPA in 1990 was to reduce the abundance of pharmacies that were in close proximity to each other, especially in major cities.

This was sought to reduce the cost to Government of supporting viability of all pharmacies, through achieving economies of scale. The number of approved pharmacies declined from 5,569 in 1989 to 4,958 in 1995, and stabilised around that level with 4,941 in 1996 and

³⁹ www.ibisworld.com/au/industry/pharmacies/1878/#IndustryStatisticsAndTrends

⁴⁰ <https://www.aihw.gov.au/reports/medicines/medicines-in-the-health-system>

⁴¹ <https://www.ato.gov.au/businesses-and-organisations/income-deductions-and-concessions/small-business-benchmarks/in-detail/pharmacy>

4,951 in 1997.⁴² The reduction in pharmacies allowed the remaining pharmacies to be more viable with a lower per unit dispensing cost as outlined in the agreement, due to a likely increase in script volume per pharmacy.⁴³ Over the last 30+ years, there has been a steady increase in the total number of pharmacies as the population has grown. As at end of June 2023, there were 5,935 approved community pharmacies in Australia. This continued growth is a further indicator of a strong community pharmacy sector. The number of pharmacies from 1995 increased by 16% while the Australian population in the same time period increased by 32%.⁴⁴

While the original intent of consolidating suburban community pharmacies to reduce oversupply of pharmacies in major cities may have anecdotally been achieved across the early years of the 1CPA, there is no quantitative evidence available to definitely determine if this realignment of pharmacies has ensured equitable access for the public to PBS medicines.

A further purpose for subsequent CPAs has been to maximise timely and affordable access to medicines and pharmacy services in rural and remote regions where dispersed population may lessen the opportunities for pharmacies to profit from other activities outside of dispensing revenue. The ongoing viability of community pharmacies is vital to ensure that timely access to medicines is possible in all communities across Australia and existing data on the number of PBS approved pharmacies (see tables 4 and 6) suggest that current mechanisms of Government intervention, including the 7CPA, have been effective in supporting both viability and distribution.

Australia has a geographically dispersed population with around 7 million people, or around 30% of the Australian population living in rural and remote areas (see Table 4 for a further breakdown of population distribution). Australia's existing community pharmacy network continues to serve as the access system for PBS medicines in the community, with pharmaceutical wholesale distributors supporting the supply chain for this network. Mechanisms, such as the Community Service Obligation (CSO) Funding Pool, are also in place to ensure that patients seeking access to medicines at pharmacies, even in the remotest areas, are assured of receiving medicines within reasonable timeframes.

The distribution of pharmacies to ensure equitable access is particularly important in rural and remote regions. A surrogate marker of remoteness is the Modified Monash Model (MMM). MMM classifications are based on the Australian Statistical Geography Standard – Remoteness Areas (ASGS-RA) framework, although 'modified' to include an overlay of town size, reflecting extensive research that the size of towns, as well as their geographic remoteness, impacts on the ability to attract and retain providers of health services. The model measures remoteness and population size on a scale of Modified Monash (MM)

⁴² plf95-c06.pdf.aspx (aihw.gov.au)

⁴³ C Sloane, *A History of the Pharmaceutical Benefits Scheme 1947–1992*, Australian Government Publishing Service, Canberra, 1995, pp. 52-59.

⁴⁴ <https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/mar-2023>

categories MM 1 to MM 7. MM 1 is a major city and MM 7 is very remote as defined in Table 4 below.

Table 4 below compares the percentage of the Australian population with the percentage of community pharmacies currently in regional and remote areas and importantly these closely align with the Australian population distribution. The geographical distribution of community pharmacies by MMM classification has been mapped in Figure 1 below. As can be seen in this figure there is a strong correlation between major population centres and the location of pharmacies, however it can also be seen that there is a widespread distribution of pharmacies outside of the urban centres.

Table 4. Modified Monash Model classifications population and pharmacy distribution

Modified Monash category	Inclusions	Australian Population*	Percentage of population	Number of community pharmacies (CP)**	Percentage of CP	Pharmacies per 1000 people
MM 1	<p>Metropolitan areas: Major cities accounting for around 70% of Australia’s population.</p> <p>All areas categorised ASGS-RA1.</p>	18,411,148	71.7%	4036	68%	0.22
MM 2	<p>Regional centres: Areas categorised ASGS-RA 2 and ASGS-RA 3 that are in, or within 20km road distance, of a town with a population greater than 50,000.</p>	2,355,589	9.2%	532	9%	0.23
MM 3	<p>Large rural towns: Areas categorised ASGS-RA 2 and ASGS-RA 3 that are not in MM 2 and are in, or within 15km road distance, of a town with a population between 15,000 and 50,000.</p>	1,640,720	6.4%	400	7%	0.24
MM 4	<p>Medium rural towns: Areas categorised ASGS-RA 2 and ASGS-RA 3 that are not in MM 2 or MM 3 and are in, or within 10km road distance, of a town with a population between 5,000 and 15,000.</p>	991,520	3.9%	268	5%	0.27
MM 5	<p>Small rural towns: All other areas in ASGS-RA 2 and 3.</p>	1,789,344	7.0%	525	9%	0.29
MM 6	<p>Remote communities: All areas categorised ASGS-RA 4 and islands that are separated from the mainland in the ABS geography and are less than 5km offshore.</p> <p>Islands that have an MM 5 classification with a population of less than 1,000 without bridges to the mainland (2019 Modified Monash Model classification only).</p>	290,660	1.1%	94	2%	0.32
MM 7	<p>Very remote communities: All other areas that are categorised ASGS-RA 5 and populated islands separated from the mainland in the ABS geography that are more than 5km offshore.</p>	206,431	0.8%	57	1%	0.28

* population based on Australian Bureau of Statistics (ABS) Estimated Resident Population (ERP) 2022 data

** number of pharmacies in each MM category as at 30 April 2023

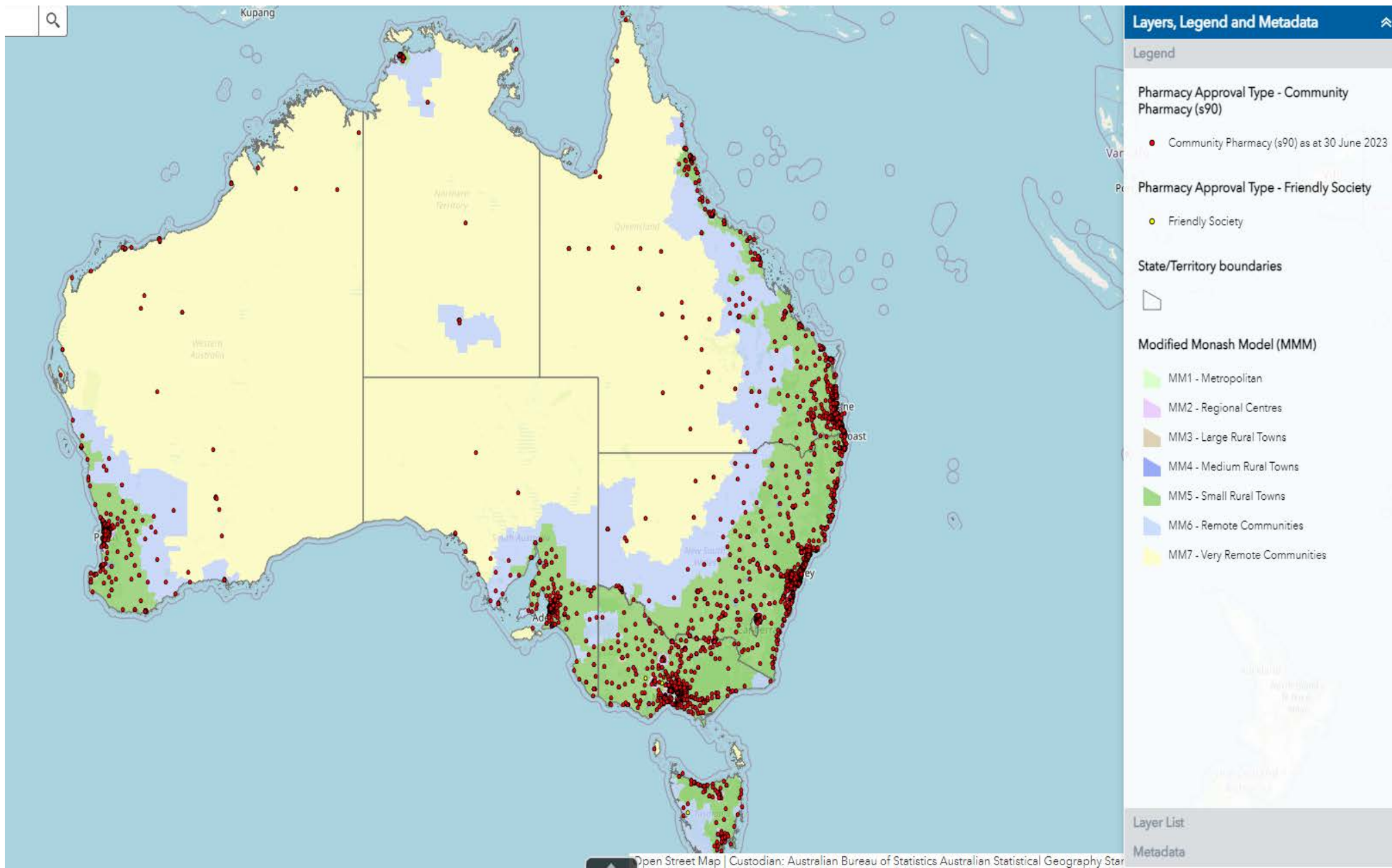


Figure 1. Distribution of community pharmacies and MM classification

Loss of pharmacies in rural and remote regions has a much more profound effect on access to PBS medicines compared to metropolitan areas where consumers can often easily access multiple pharmacies. In addition the National Health Survey found that in 2020-21, approximately one quarter (24.5%) of people living in inner regional Australia were supplied with five or more medication types, compared to 17.4% living in major cities. The average number of medications dispensed was similar in major cities (3.7), inner regional Australia (4.2), outer regional and remote Australia (4.0).⁴⁵

Successive CPA agreements have provided specific funding for rural and remote pharmacy and pharmacists. The 7CPA continues to support rural programs including the Regional Pharmacy Maintenance Allowance (RPMA), which provides funding to eligible pharmacies depending on their location and how many prescriptions they fill as well as the following lower volume programs:

- Rural Continuing Professional Education Allowance (CPE)
- Emergency Locum Service (ELS)
- Rural Intern Training Allowance (RITA)
- Rural Pharmacy Scholarship Scheme (RPSS)
- Rural Pharmacy Scholarship Mentor Scheme (RPSS-Mentor)
- Rural Pharmacy Liaison Officer Program (RPLO)
- Rural Pharmacy Student Placement Allowance Program (RPSPA)
- Administrative Support to Pharmacy Schools Scheme (Admin)
- Intern Incentive Allowance for Rural Pharmacies (IIARP)
- Intern Incentive Allowance for Rural Pharmacies Extension program (IIARP-EP)

For the first year of the agreement the funding allocated was \$24.6 million for the rural support program to be increased year on year during the agreement. This is in addition to the funding for the Aboriginal and Torres Strait Islander Specific Programs which were allocated a further \$12.6 million in the first year of the CPA. In 2022-23 the total expenditure for the RPMA was almost \$20 million and supported almost 1,100 pharmacies. Table 5 below outlines the expenditure for the RPMA in 2022-23 in more detail.

From 1 July 2023, the budget for the RPMA doubled to \$39.8m per year. This represents \$79.5 million over 4 years to ensure Australians in regional, rural, and remote locations have continued access to pharmacies and pharmacy services. The total number of active service providers receiving the RPMA has continued to slowly increase to 1,149 in November 2023 from 1,068 in July 2022.

⁴⁵ <https://www.abs.gov.au/articles/pharmaceutical-benefits-scheme-supplied-medications>

Table 5. RPMA expenditure 2022-23

Year	Month	Total Number of Active Service Providers*	Expenditure
2022	July	1,068	\$1,653,082.40
2022	August	1,076	\$1,644,751.17
2022	September	1,080	\$1,645,780.53
2022	October	1,083	\$1,651,483.95
2022	November	1,081	\$1,642,522.36
2022	December	1,084	\$1,651,232.93
2023	January	1,081	\$1,641,627.94
2023	February	1,086	\$1,647,790.93
2023	March	1,093	\$1,658,719.60
2023	April	1,095	\$1,661,084.02
2023	May	1,098	\$1,663,411.61
2023	June	1,097	\$1,643,841.11
Total Paid 2022-23			\$19,805,328.55

* The total number of service providers is not cumulative. A service provider is considered 'active' if they submitted a claim in relation to the program during the month

While the number of approved pharmacists increased year on year over the 6CPA and 7CPA the ratio of approved pharmacists in urban (MM1) versus rural areas (MM2-7) has shown little variation over this time. There is a very slight increase in the percentage of rural pharmacies over time (Table 6) however this data indicate that overall there has not been an increase in closures in rural and remote areas over time compared to urban areas.

Table 6. PBS approved pharmacies in urban and rural areas as at 31 December 2017 – 2023

Year	No. in Urban MM1	No. in Rural MM 2-7	% Urban	% Rural
2023	4,050	1,885	68.24%	31.76%
2022	4,029	1,872	68.28%	31.72%
2021	4,010	1,865	68.26%	31.74%
2020	3,975	1,847	68.28%	31.72%
2019	3,942	1,820	68.41%	31.59%
2018	3,911	1,812	68.34%	31.66%
2017	3,872	1,792	68.36%	31.64%

To support an effective distribution and supply chain for PBS medicines across Australia, successive CPAs have further included wholesaler mark-ups as well as CSO Funding Pool payments to pharmaceutical wholesalers. These arrangements ensure that patients in rural and remote regions are able to access the PBS medicines they need in a timely manner. The Department has analysed data on the distribution of

CSO services delivered broken down by MM location for the past 2 financial years in Table 7 to provide a proxy for the extent to which medicines are being delivered equitably to rural and remote communities.

Table 7. CSO supply of units per MM classification

MM Cat		2021-22		2022-23	
		CSO Units	% total	CSO Units	% total
1	Metropolitan areas	268,337,151	68.9%	279,558,845	69.1%
2	Regional centres	37,727,398	9.7%	38,643,752	9.6%
3	Large rural towns	34,947,723	9.0%	35,937,581	8.9%
4	Medium rural towns	21,367,440	5.5%	22,130,687	5.5%
5	Small rural towns	22,107,075	5.7%	22,815,256	5.6%
6	Remote communities	3,583,347	0.9%	3,561,997	0.9%
7	Very remote communities	1,574,646	0.4%	1,642,810	0.4%
Total		389,644,780		404,290,928	

Stakeholders have claimed that in the absence of this level of intervention in the pharmacy marketplace the relatively convenient and affordable availability of PBS medicines within the community may not be assured, with people living in rural and remote areas most likely to experience greater distance barriers to access community pharmacies. This would make it difficult or expensive for consumers to access prescription medicines and may result in a broadening of the existing gap between health outcomes for Australians living in urban as opposed to more regional locations.⁴⁶

Quality use of medicines and medicines safety

Taking the wrong medicine or too much of a prescribed medicine can be dangerous and even life-threatening and evidence indicates that most accidental poisonings involve medicines. The more medicines an individual takes, the higher the risk of potential harm. In Australia, accidental poisoning resulted in approximately 8,800 hospitalisations in 2021-22, and of these 7,093 were related to pharmaceuticals. People living in very remote areas, using age-standardised rates, were 1.5 times as likely to be hospitalised for accidental poisoning as those living in major cities.⁴⁷ The factors influencing this are varied but include a larger Indigenous population percentage in very remote regions with Indigenous Australians 3.1 times more likely than non-Indigenous Australians to be hospitalised by accidental poisoning.⁴⁸ The overall rate is also likely to be influenced by the accessibility of agricultural pesticides in rural communities⁴⁹, however a report in 2001 on accidental poisoning in pre-schoolers from medicinal products found that “The incidence rates were highest in rural and remote areas. The rate for remote centres was significantly higher, statistically, than the rate for all other areas, with the

⁴⁶ <http://ruralhealth.org.au/sites/default/files/documents/nrha-policy-document/policy-development/nrha-medicines-discussion-paper-january-2014.pdf>

⁴⁷ www.aihw.gov.au/reports/injury/accidental-poisoning

⁴⁸ <https://www.aihw.gov.au/reports/injury/accidental-poisoning#Remote>

⁴⁹ Disadvantaged by More Than Distance: A Systematic Literature Review of Injury in Rural Australia, Safety, Vol 8, Issue 3, 2022 <https://www.mdpi.com/2313-576X/8/3/66>

exception of other remote areas. The remote centre rate was about 2.7 times higher than the capital city rate. All of the rural and remote area rates were significantly higher, statistically, than the capital city and other metropolitan centre rates⁵⁰. While packaging changes including child-resistant packaging⁵¹ and labelling have gone a long way to reduce the incidence overall of accidental medicinal poisoning the role of the community pharmacist in educating consumers in rural and remote regions on the danger posed by accidental poisoning remains of importance.

To protect the Australian public all medicines supplied in Australia are regulated by the TGA. Within this role, in addition to ensuring each medicine meets the required standards of quality, safety and effectiveness for the intended use, the TGA assesses the potential risks and classifies medicines into schedules (The Poisons Standard which may also be cited as the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)) according to the level of regulatory control required to protect health and safety. These schedules determine whether a medicine is a pharmacy, pharmacist only or a prescription only medicine. This ensures that medicines where appropriate can only be dispensed by a pharmacist who is trained to safely dispense them and provide the necessary additional supporting information to the patient.

As part of their core function pharmacists use their expertise in medicines to optimise health outcomes and minimise medication misadventure. They apply their knowledge of medicines and poisons to ensure that patients not only get the correct medication and dosing, but that they have the guidance they need to use the medication safely and effectively. Dispensing remuneration in part provides funding to support pharmacists in undertaking the relevant checks and consulting with patients when required to minimise the chances of adverse events occurring from the prescribed medicines.

A number of CPPs implemented through successive CPAs have sought to provide an additional level of support above and beyond fundamentals like scheduling of medicines to further reduce this risk. Relevant CPPs included in the 7CPA include the provision of dose administration aids (DAAs), where medicines are packed in individual time and day separated compartments to aid in medication adherence by consumers, and undertaking medication reviews both in the home and in the pharmacy.

Data for relevant pharmacy programs, including DAAs, are monitored and published monthly on the Department's website at www.health.gov.au/resources/collections/pharmacy-programs-data. The data available largely relate to volumes and expenditure and while this provides some insight to the need for such programs, further improvements could be made by developing and implementing approaches to monitor and evaluate the health outcomes achieved through each of the programs. Demand for DAAs has continued to grow significantly over time since the introduction of this program in 2005. In the 2022-23 financial year over 16 million DAAs were made available by more than 5000 providers to assist patients with taking medications at home.

Studies have shown that the use of DAAs or similar medicine compliance aids can significantly improve adherence to certain medications, however these studies have generally included significant

⁵⁰ <https://www.aihw.gov.au/getmedia/81573af6-3fbc-4848-a23c-0952cc3f27d6/injcat39.pdf?v=20230605182328&inline=true>

⁵¹ <https://www.injurymatters.org.au/programs/know-injury/know-poisoning/>

methodological limitation, inadequate length of follow-up, and moderate-to-high risk of bias. These studies often focus on a narrow aspect, such as limited population or a particular type of DAA. Furthermore, studies may be limited in their geographic scope or setting, which further restricts the generalisability of their findings. This results in the gaps in our understanding of a comprehensive picture of DAAs within the primary care setting, including community pharmacy. In addition, improved medication compliance, is not necessarily accompanied by clinically meaningful improvements in clinical outcomes as modest amounts of non-adherence may still leave patients within a therapeutic window. There are also a number of confounding factors that make it difficult to assess the effectiveness of this longstanding program, including changes to the patterns of medicine use over time.

Over the five years to 2020, more than half of all unintentional drug-induced deaths involved three or more drug types, with pharmaceutical opioids involved in half of all poly-substance deaths during the five-year period. Unintentional poly-substance deaths were most commonly seen in middle aged persons, although they were responsible for almost two-thirds of unintentional drug-induced deaths among women aged 60 and above. From 2001 to 2020, during which the population of Australia increased by 31.6%, there was a disproportionately greater increase (68.6%) in the number of unintentional drug induced deaths, from 981 to 1,654.⁵²

The 6CPA suggested that CPPs would be subject to a cost effectiveness assessment by an independent health technology assessment body (such as the Medical Services Advisory Committee (MSAC) or PBAC) as determined by the Minister. To this end MSAC consideration of the available data on existing pharmacy programs including staged supply, DAAs and clinical interventions occurred in November 2016. However they found it was difficult to conduct a comparative assessment of these programs as they were by that time primarily standard of care expected of a pharmacist. They considered that an option might be to conduct a comparative assessment of future proposed improvements to these practices, which could justify the provision of program funding for the enhanced services. MSAC further suggested that funding for the existing pharmacy programs should continue while these protocols for novel ways to enhance services were developed by the pharmacy sector.⁵³

The 7CPA indicated that the Commonwealth would undertake or commission an assessment of Commonwealth funded services under the CPPs during the life of the agreement to identify and assess the outcomes, efficiency and effectiveness of such programs. In line with this intent, the Department has commissioned the University of Sydney to undertake an assessment of the largest program under the CPP, the DAA program, which accounts for annual expenditure of approximately \$100 million. The assessment will collect input from pharmacists delivering the program and consumers and/or their carers. One of the key aspects to be investigated is which patient populations receive the most benefit from this program and if necessary how the program could be better adjusted and or targeted to deliver the most effective outcomes.

Initial suggestions from this work include:

⁵² <https://www.penington.org.au/wp-content/uploads/2022/09/Penington-Institute-AAOR-2022.pdf>

⁵³ www.msac.gov.au/internet/msac/publishing.nsf/Content/6CPA-PPI%20Programs-public

1. *Ensuring that there are up-to-date national guidelines available and implemented for the packaging and delivery of DAAs*
2. *Using standardised, valid and reliable measures of adherence to allow for comparison between studies*
3. *Ensuring that in commencement of DAAs the pharmacist reviews the potential barriers to DAA use by the patient/carer; and conducts a medication reconciliation or review of the patient's medications, and*
4. *Promoting research into the economic aspects of DAA implementation to better understand the economic impact of DAAs and their cost-effectiveness within a wider demographic population and geographic area.*

The initial suggestions will be further refined throughout the remaining phases of the assessment which is expected to be finalised in mid-2024. The outcomes will inform any future consideration of reform of the DAA program.

While successive CPAs have increased access to CPPs, a number of consulted stakeholders have indicated that agreement to pharmacy remuneration for the dispensing of PBS medicines should be separated from the funding agreements for the delivery of CPPs. This would allow CPPs to be developed with a broader range of relevant stakeholders over more flexible timeframes and enhance the potential for innovation, including through take-up and evaluation of outcomes.

Separation of CPPs from the CPA is also consistent with the most recent review of community pharmacy remuneration as outlined in section 1.7 above which suggested that "...the value of the CPA process would be maximised if CPAs were more closely focused on the dispensing of PBS medicines, those services directly related to the dispensing function and responsibilities, and the pricing to consumers for such dispensing." It further states that "the CPA is not the right mechanism to attempt to capture broader health programs and services or supply chain activities. These involve multiple key stakeholder groups and extend beyond the funding of PBS-related services."

Collaborative, innovative and sustainable pharmacy industry

CPAs have supported collaboration and innovation in the pharmacy sector, particularly through CPPs. Current funding for CPPs as outlined in the 7CPA is focussed on 4 key areas with funding for each program area increasing year on year for the life of the 7CPA as outlined below in Table 8. An overview of the CPPs included in the 7CPA is provided at Appendix 5. Demand for many programs is greater than anticipated at the beginning of the 7CPA.

Table 8. Community Pharmacy Program Expenditure

Community Pharmacy Programs	2020-21 (Actuals) (\$m)	2021-22 (Actuals) (\$m)	2022-23 (Actuals) (\$m)
Medication Adherence Programs: - Dose Administration Aids - Staged Supply	106.3	107.2	109.6
Medication Management Programs - Home Medicines Review - Residential Medication Management Review - Quality Use of Medicines in Residential Aged Care Facilities - MedsCheck/Diabetes MedsCheck	88.5	89.5	101.6
Aboriginal and Torres Strait Islander Specific Programs - Indigenous Dose Administration Aids* - Indigenous Health Service Pharmacy Support Program* - QUMAX/S100 Pharmacy Support Allowance** - Aboriginal and Torres Strait Islander Workforce Programs - CTG	12.2	21.4	26.0
Rural Support Programs - Regional Pharmacy Maintenance Allowance - Rural Workforce Programs	21.0	22.5	22.7
eHealth - Electronic Prescription Fee	22.6	29.5	35.8
Other activity	8.5	9.0	9.1
Total (\$m)	\$259.1	\$279.1	\$304.8

Notes:

This table is reflective of Commonwealth Expenditure as of 30 June 2023⁵⁴

** Commenced 1 July 2021*

*** Ceased 30 June 2021*

**** EPF is no longer funded under the 7CPA as of 2023/24 budget.*

Internationally, some pharmacists are funded either by governments or by patients to deliver additional services such as ordering laboratory tests, screening patients, treating minor ailments, and implementing chronic care plans prepared by medical practitioners. The potential for innovation

⁵⁴ <https://www.health.gov.au/resources/collections/pharmacy-programs-data>

through the establishment of similar pharmacy programs for patients in Australia has been explored through funded trials. Trials undertaken under the 6CPA for example aimed to temporarily fund new services that expanded the role of pharmacists to include delivering primary health care and to improve clinical outcomes for consumers. Eight Pharmacy Trials were funded, and the trial outcomes were subject to an independent assessment by MSAC to inform whether they should be publicly funded for broader rollout. The trials were in the following areas:

- Pharmacy Diabetes Screening Trial (PDST)
- Improved Medication Management for Aboriginal and Torres Strait Islanders (IMeRSe) Feasibility Study
- Integrating Practice Pharmacists into Aboriginal Community Controlled Health Services (IPAC) Project
- Reducing Medicine Induced Deterioration and Adverse Reactions (ReMInDAR) Trial
- Getting your Asthma Under Control Using The Skills of the Community pharmacist
- Chronic Pain MedsCheck (CPMC) Trial
- Bridging the Gap Between Physical and Mental Illness in Community Pharmacy (PharMIbridge) Trial
- Early Detection, and
- Management of Cardiovascular Disease (CVD) Risk Factors and Chronic Disease Markers in Community Pharmacy

MSAC has considered all eight trials but it has only recommended support for the broader rollout of a program to integrate pharmacists into Aboriginal Community Controlled Health Organisation (ACCHOS) and Aboriginal Health Service (AHS) multidisciplinary care teams in line with the trial⁵⁵ which was undertaken as a collaborative partnership between James Cook University, the PSA and NACCHO. Opportunities for the implementation of this program are continuing to be explored. For all other trials under the 6CPA, MSAC has not recommended support due to insufficient evidence of benefit, with further or stronger evidence needing to be collected in most cases.

To maximise efficiencies and ensure ongoing sustainability it is essential that pharmacy programs continue to encourage collaboration and innovation and make the most of opportunities to improve health outcomes for all Australians. This will be particularly relevant as the use of personalised medicine approaches increases.

Many stakeholders, with the exception of the Guild, have indicated that existing arrangements for the identification, design and agreement to pharmacy programs could be enhanced by separating program funding from the CPA to increase the opportunities for engagement with a broader range of stakeholders including consumers, state and territory governments, regulators, pharmaceutical manufacturers, wholesalers, and pharmacy organisations.

⁵⁵ <https://www.health.gov.au/sites/default/files/2023-06/integrating-practice-pharmacists-into-aboriginal-community-controlled-health-services-final-report.pdf>

2. Why is government action needed?

The provision of safe, effective and affordable medicines plays a fundamental role in the delivery of health services in Australia as part of our universal health system. If Australians were unable to access PBS medicines through community pharmacies this could have a detrimental impact on the broader health system through escalating illness and the spread of disease, and lead to greater subsequent costs incurred through the need to treat people in a hospital or similar setting.

To support the effective implementation of the PBS, to achieve the objectives of the National Medicines Policy, Government action is required to determine the Commonwealth price for the dispensing of PBS medicines consistent with the Act. As outlined above, there are two legislated options for determining the payments approved pharmacists receive for dispensing PBS medicines, either an agreement between the Commonwealth and the Guild which is then ratified by the PBRT, or if there is no agreement in place through a decision of the PBRT.

The major benefit to both Government and industry from establishing the level of dispensing remuneration by agreement is that it is a known quantum of expenditure for Government and revenue for community pharmacy over the life of the agreement with the only variable being the number of qualifying scripts in each year. If the Commonwealth price was set by the PBRT there would be a period of uncertainty while the PBRT completed its inquiry and for both future Government expenditure and community pharmacy revenue as the outcome of the inquiry would be unknown. In addition the timeframes for completion of the inquiry would be unknown and difficult to estimate. This could lead to loss of business confidence by pharmacy owners and result in undesirable outcomes for patients, for example higher than expected closures or reduction in opening hours and services offered through community pharmacies.

Supporting accessible and affordable medicines through community pharmacy via patient subsidies falls to the Commonwealth and this is an uncontested space. There are no constitutional or other barriers to the Commonwealth making PBS medicines available to Australians through the community pharmacy network with the support of appropriate funding for this work.

Pharmacists have the necessary training and skills to ensure that consumers receive the correct medicines in the appropriate doses as prescribed by doctors and the network of community pharmacies ensures adequate availability of this service across the country. It is a long-standing arrangement that the Commonwealth has provided financial support to community pharmacies to make available PBS medicines to Australians in a secure and equitable matter. This funding has been revised from one CPA to another to reflect changes in costs incurred by pharmacies and to support the viability of pharmacies so that they can continue to provide this service.

The Government has committed to explore options for a new CPA, which would commence earlier than the expiry of the current agreement, following the implementation of the 60 Day Dispensing measure. This provides an opportunity for implementation of further reforms to reflect a modern regulatory and policy environment in alignment with the NMP.

To support the four pillars outlined earlier the NMP identifies a set of fundamental principles to guide the development, implementation and evaluation of related policies, strategies, programs and initiatives. These principles and associated actions include:

- **person-centred** – consumers are supported to be active participants in decision-making, including developing health, digital and medicines literacy
- **equity and access** – all reforms should focus on delivering and achieving health outcomes that matter most to people and their communities, and deliver positive, culturally safe and appropriately targeted ways to eliminate health inequities that are experienced by vulnerable population groups within the Australian community
- **partnership-based and shared responsibility** – respectful and ongoing dialogue, collaboration and cooperation is maintained between partners
- **accountability and transparency** – all partners accept responsibility for and are held accountable for advancing progress of the NMP’s central pillars
- **innovation and continuous improvement** – reforms support new and improved ways to identify and respond to current and future health needs, and to achieve the best health, social and economic outcomes for all Australians
- **evidence-based** – all partners apply relevant, current and context-specific evidence and consensus best practice to guide decision-making, program design and communication, and
- **sustainability** – all partners focus on optimising medicines use and consider the health, social and economic impact and sustainability of policies, programs or initiatives under the agreement.

To further guide consideration of the negotiation of a new community pharmacy agreement, the specific objectives outlined in Table 9 below were developed in alignment with the above principles and broader NMP. These objectives have been used to aid in the development and consideration of potential options for future arrangements for determining dispensing remuneration and CPP arrangements.

Table 9. Policy objectives

Objectives of Government	Intended outcome
<p>Person-Centred – Dispensing & Programs</p> <p>Enables consumers to be well informed and make active decisions in accessing their PBS medicines. This includes developing and building health and medical literacy.</p>	<p>Consumers are able to access detailed, timely and easy-to-understand information on the safe use of PBS medicines. Where appropriate consumers are also supported by pharmacy programs which further enhance health and medical literacy and consumer views and feedback informs the design and ongoing improvement of relevant CPPs.</p>
<p>Equity, sustainability and Access for Consumers</p> <p>Supports timely, affordable, safe and reliable access to medicines and pharmacy services and seeks to reduce inequities that are experienced by vulnerable population groups</p>	<p>Consumers can access PBS medicines in a timely manner irrespective of their geographical location.</p>

within the community including First Nations people and people living in rural and remote areas.	
Equity, sustainability and Access for Businesses Supports the ongoing availability of PBS medicines through community pharmacies regardless of geographical location.	Provides for timely supply of PBS medicines, including in remote and regional areas.
Accountability and Transparency Supports the availability and sharing information on medicine and dispensing costs in a respectful, ethical and transparent way.	Prior to a medicine being dispensed, consumers are able to access through their pharmacy easy-to-understand information on the costs they will incur in accessing PBS medicines.
Innovation and Continuous Improvement Encourages innovation and the continued improvement of pharmacy services.	Supports the collection and evaluation of evidence/data on the impact pharmacy services have on health outcomes.

Person-centred

Consumers are currently provided, and actively seek, information through community pharmacies on the safe use of medicines as a part of the core pharmacy services. In addition to these core services, CPPs which focus on medication management and review also support a consumer focus and building individual health literacy to achieve the best health outcomes possible. However some of these programs have been in place for many years and were developed with minimal engagement with consumers or consumer representatives. Many stakeholders have suggested that CPPs could be better targeted and should be developed with a broad range of stakeholders to ensure the best health outcomes.

Consumers Health Forum of Australia (CHF) suggested as a part of their submission to the Review of Pharmacy Remuneration and Regulation Discussion paper in 2016⁵⁶ that the pharmacist's role in providing consumers with information about their prescription medicines should be explicitly included in the dispensing fee. Consumers should be involved in the development of the statement about provision of advice and information. However CHF noted that it is hard to monitor the provision of advice and information and the compliance monitoring and reporting required to enforce it would be prohibitive and therefore did not suggest that there should be a separate payment for this role.

In the same submission CHF stated that there should be separate negotiations and agreements on the dispensing fee and the professional services program.

⁵⁶[https://web.archive.org/awa/20220816160934mp_/https://www1.health.gov.au/internet/main/publishing.nsf/Content/review-pharmacy-remuneration-regulation-submissions-cnt-10/\\$file/483-2016-29-09-consumers-health-forum-of-australia-submission.pdf](https://web.archive.org/awa/20220816160934mp_/https://www1.health.gov.au/internet/main/publishing.nsf/Content/review-pharmacy-remuneration-regulation-submissions-cnt-10/$file/483-2016-29-09-consumers-health-forum-of-australia-submission.pdf)

Impacts in relation to this objective will therefore be measured through the potential to deliver greater inclusion of consumer representative stakeholders in the establishment of evaluation frameworks for existing CPPs relating to medication management and review and in future CPP development.

Equity, sustainability and access for consumers

Successive CPAs have sought to support timely, affordable, safe and reliable access to medicines and pharmacy services for all Australians. As outlined earlier, access is particularly relevant to consumers in regional and remote areas. In 2017–18, based on self-reported data from the National Health Survey and after adjusting for age, people living outside major cities had higher rates of arthritis, asthma and diabetes. People living outside major cities however were found to use chronic disease management services less, which could be due to a number of reasons including availability of services or the health and age of the population within an area.⁵⁷

Differences in indicators of health between urban and remote or regional areas are due to a range of factors and it is not possible to specifically identify the contribution which one factor, such as availability and access to pharmacy services, contributes to measures of population health. Accordingly, the specific contribution to health outcomes made due to the services funded under a particular CPA, or from one CPA to another, are difficult to isolate. Nevertheless, the role of available pharmacy services is recognised by all industry stakeholders as a key factor in achieving positive population health outcomes.

Impacts against this objective will be measured through the continued relative distribution of pharmacies and monitoring of pharmacy opening and closure data. In addition, patient access will be considered through PBS script volumes and the total cost to patients for medicines priced below the level of the patient co-payment (i.e. patient contributions through under co-payment prescriptions).

Equity, sustainability and access for businesses

Equity, sustainability and access for business is similar to that outlined above for consumers noting that viable pharmacies which are able to supply the PBS medicines as needed in the relevant local area ultimately support consumer access. Pharmacies are currently supported in achieving the objective primarily through dispensing remuneration for PBS medicines as outlined in successive CPAs.

Mechanisms such as the wholesale mark-up fee and the CSO arrangement also ensure that PBS medicines are available to all pharmacies regardless of location, within a reasonable timeframe. A number of CPPs are also in place to specifically support pharmacies in rural and remote locations.

Community pharmacies operate in a complex regulatory environment with unique and longstanding restrictions on location, ownership, and pricing of PBS medicines. Many of these arrangements are implemented and operate independently of the CPA and are therefore outside scope. In previous CPAs such arrangements have however been referenced and there may be opportunity to better focus the scope in future arrangements to avoid potential confusion.

As noted previously, the Government announced an additional \$79.5 million in funding over four years for rural and remote pharmacies to provide additional assistance to pharmacy owners. This addressed

⁵⁷ <https://www.aihw.gov.au/reports/rural-remote-australians/rural-and-remote-health>

an expected lowering in dispensing revenue from the introduction of the increased MDQ measure from 1 September 2023. These measures are funded up to Financial Year (FY) 2026-27 and were committed to outside of the 7CPA.

The MDQ measure will reduce the amount of remuneration that community pharmacies receive from dispensing certain PBS medicines that are prescribed with an increased maximum quantity. Public statements made by representative organisations including the Guild and individual pharmacists suggested that the changes would lead to shorter opening hours, firing of staff, and possibly closure of some pharmacies.

No evidence available to the Department to date supports the claims from concerned pharmacists and pharmacy organisations that introduction of MDQ will lead to pharmacy closures (due to loss of viability) or increased medicine shortages. Following the announcement of MDQ the number of pharmacy approval cancellations and new pharmacy applications submitted to the Department has been similar to the number of applications received over the same period in the previous year (see Table 10). The Department is however committed to monitoring stakeholder impacts through existing mechanisms in implementing the MDQ measure.⁵⁸

Table 10. Pharmacy approval data MDQ announcement on 26 April 2023

	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	Total
Applications for new pharmacies									
1 May 2023 to 31 December 2023	18	11	28	19	7	2	1	1	87
1 May 2022 to 31 December 2022	8	20	19	5	5	2	0	0	59
September 2023 only	0	1	1	2	0	1	0	0	5
Approvals of new pharmacies									
1 May 2023 to 31 December 2023	4	11	14	3	2	1	0	0	35
1 May 2022 to 31 December 2022	4	10	6	6	4	2	0	0	32
September 2023 only	1	1	3	0	0	0	0	0	5
Pharmacy approvals cancelled* (Closures)									
1 May 2023 to 31 December 2023	1	2	2	0	1	0	0	0	6
1 May 2022 to 31 December 2022	2	2	0	0	0	0	0	0	4
September 2023 only	0	1	0	0	1	0	0	0	2

* Approval cancellations may be the result of a request from the approved pharmacist or a decision by a delegate where the pharmacy is no longer trading. This may be in situations where the pharmacy business is no longer viable, or for commercial reasons such as leasing issues.

As with equity, sustainability and access for consumers, impacts against this objective will primarily be considered by the potential to affect pharmacy distribution as monitored through pharmacy opening and closure data. This will be further informed by consideration of the estimated impacts on the total dispensing remuneration provided to pharmacies, specific Commonwealth funding for rural and remote pharmacies and CSO/wholesaler arrangement data.

⁵⁸ <https://oia.pmc.gov.au/published-impact-analyses-and-reports/lowering-costs-medicines-through-changes-maximum-dispensing>

Accountability and Transparency

A number of publically available government and retail resources seek to explain the cost of PBS medicines in a simple way. This includes information available on PBS fees, patient contributions and safety thresholds available on the Department website,⁵⁹ the Services Australia website⁶⁰ and the Health Direct website.⁶¹ In addition, as required under the 7CPA, the Guild currently publishes a breakdown of costs incurred by consumers for dispensing PBS medicines on its website.⁶² The Guild is also required to use its best endeavours to ensure that individual pharmacists and pharmacies provide this information to consumers at the time of dispensing.

This information however may not provide the level of detail sought by consumers as it is typically generic rather than being specific to the medications being supplied. Impacts against this objective will therefore be considered in relation to the potential to increase availability of information and consumer awareness of PBS medicine costs, including any additional pharmacy charges, prior to dispensing.

Innovation and Continuous Improvement

Successive CPAs have sought to encourage innovation and the continued improvement of pharmacy services through a range of CPPs. However as outlined earlier in many cases the actual health benefits being achieved are uncertain. Key stakeholders have suggested that CPPs should only continue if supported by quality and evaluation frameworks which provide for robust analysis noting that this may be best achieved if CPPs were agreed outside of the CPA.

Impacts against this objective will therefore be considered in light of the anticipated ability of each option to facilitate the establishment of quality and evaluation frameworks with the review of CPPs.

Potential Barriers to the Government Meeting its Objectives

The extent to which the Government is able to meet the objectives above will be dependent on achieving the support and agreement to Government's preferred approach through negotiation with the Guild and other relevant stakeholders.

Additional challenges in reaching agreement include:

- the preferred timeframes for completing negotiations for an 8CPA prior to the expiry of 7CPA
- balancing the views and concerns of multiple stakeholders who do not agree on key issues in reaching an agreement
- the complex inter-play between existing arrangements for community pharmacy as achieved through the CPA and other mechanisms, and
- agreement of Government to an approach and the overall funding envelope for remuneration.

⁵⁹ <https://www.pbs.gov.au/info/healthpro/explanatory-notes/front/fee>

⁶⁰ <https://www.servicesaustralia.gov.au/pharmaceutical-benefits-scheme>

⁶¹ <https://www.healthdirect.gov.au/pharmaceutical-benefits-scheme-pbs>

⁶² <https://www.findapharmacy.com.au/pbs-pricing>

To manage the above barriers the Department has and is continuing to undertake extensive consultation and hold regular meetings with a range of affected stakeholders including the Guild, PSA, NACCHO and relevant areas of government.

3. What policy options are you considering?

As outlined above there are only two options for determining the Commonwealth price for the dispensing of PBS medicines consistent with the Act, either an agreement between the Commonwealth and the Guild which is then ratified by the PBRT, or if there is no agreement in place through a decision of the PBRT. While a wide range of options for a potential new CPA were explored early on in the development of this policy, most of these options would not lead to an acceptable outcome for the Government or were considered unlikely to offer a pathway to an agreement and would have resulted in reverting back to Option 1. These options are not explored further in this assessment and broadly, in light of the stakeholder feedback it was considered that there were three main options.

These options, as considered in this IA are:

- Option 1: Continuation of the 7CPA until 30 June 2025 and no new CPA following its expiry, unless one can be negotiated before this date (Status Quo)
- Option 2: Establish an 8CPA that includes all existing pharmacy programs
- Option 3: Establish an 8CPA for dispensing remuneration and only pharmacy programs delivered directly through community pharmacies

Option 1: Continuation of the 7CPA until 30 June 2025 and no new Community Pharmacy Agreement following its expiry (Status Quo)

Should the 7CPA expire on 30 June 2025 and not be replaced with a new agreement, existing processes and ongoing funding commitments from Government would ensure that a number of critical aspects of the funding for community pharmacies would continue to operate as per the 7CPA. However, some programs and services would need to be managed through new approaches, as outlined below:

- Dispensing remuneration would be independently determined by the PBRT. Until such a determination by the PBRT was undertaken, remuneration to pharmacists for dispensing PBS medicines would remain at the level set at the cessation of the 7CPA.
- The PBRT would be required to hold an inquiry to ascertain whether the Commonwealth price should be varied. In carrying out the inquiry the PBRT may approve criteria that it considers to be appropriate for use in determining the nature or magnitude of fees or other amounts, and may, at any time, vary or revoke such criteria.
- In determining fees or other amounts and in approving criteria, the Tribunal must have regard to national minimum wage orders of the Fair Work Commission, and, in particular, any statements by the Commission about the effect of wage increases on productivity, inflation and levels of employment (sections 98B and 98BA of the Act).
 - Once a level of remuneration is determined the Government could undertake a communication strategy to explain the cost of medicine to consumers. However unlike

the CPA there would not be a commitment to improve transparency of pricing for individuals at the pharmacy level.

- CPPs delivering services to consumers (such as medication management and review programs) would continue as outlined in the 7CPA while they are formally evaluated separately by the Department and actions taken to ensure they are delivering on intended outcomes. Ongoing funding of some existing CPPs was agreed as part of the 2023-24 Budget and changes to these programs, to make them more patient centric, could be made by the Government through normal policy and funding decision-making processes.
- NDSS arrangements would require discussion with the National Pharmaceutical Services Association (NPSA), the peak body representing wholesalers, and non-NPSA wholesalers before expiry of the 7CPA or as soon as practical thereafter. Longer term, alternative arrangements for direct delivery of NDSS products to consumers could be investigated, with public approaches to market for organisations with capability to manage and distribute these products.
- CSO arrangements including those outlined in the 7CPA and the individual CSO contractual arrangements with the six current CSO providers would likely require renegotiation. The parameters for these contractual arrangements would be subject to renegotiations with NPSA and the relevant wholesalers.

Adoption of this option would lead to the most business uncertainty for community pharmacy as there would be no forward agreement on what remuneration pharmacies would receive from dispensing PBS medicines. In the absence of a CPA the Government could separately undertake reviews of the CPPs to establish which programs are delivering clinical benefit and what if any changes should be made to better tailor the programs to deliver the best clinical outcomes and encourage innovation. However, due to the uncertainty created in the sector in the absence of a CPA, stakeholders may be less likely to engage in the reviews or support innovation through significant program changes.

Stakeholder roles and responsibilities

Consumers

- There should be no initial change in patient access to PBS medicines.
 - Medicines should still be available at community pharmacies as wholesalers would still be required to supply medicines under the individual CSO agreements.
 - While there should be no immediate change to community pharmacies that would affect their opening hours or profitability that would result in pharmacy closures, uncertainty may result in certain business decisions even prior to a PBRT determination, which may limit access for some consumers, particularly if pharmacies in rural and remote regions close.
 - If some pharmacies close due to this option, (see Pharmacies below) access to PBS medicines for some consumers may become more restricted.
- Prices for medicines under the PBS general patient co-payment may change after PBRT makes a determination of the Commonwealth price.
- Consumers and representative consumer organisations would be asked for input into the evaluation and possible changes to CPPs after the expiry of the 7CPA.

Pharmacies

- Pharmacies would continue to dispense PBS and non-PBS medicines as before.

- Pharmacies would not receive any immediate increases in remuneration at the conclusion of the 7CPA. Remuneration would remain at the same levels per script dispensed until a PBRT determination was made.
 - There would be no agreement on the future projection of dispensing remuneration.
 - Based on pharmacist feedback and industry press,⁶³ business confidence in the sector could fall with some owners possibly looking to sell or close some pharmacies.
- CPPs and their administration processes would continue largely unchanged while they are formally evaluated by the Department in consultation with stakeholders. Pending further stakeholder discussions, CPPs could include a requirement for additional data capture by pharmacies to enhance health outcome data, in addition to requirements under any quality and evaluation frameworks.
 - This would allow Government to more accurately consider in the future which programs are of the greatest clinical benefit and most cost-effective. However, outcomes of future consultations are not possible to be predicted and potential impacts of any changes proposed once known would need to be considered in full.
- In the short term, pharmacies' practical access to PBS medicines may not change, as in addition to the 7CPA, current wholesalers have individual contracts with the Commonwealth, which could ensure continued supply of medicines in the short term. Once new individual CSO arrangements are finalised, new wholesaler contracts will be required which may change overall access.
- NDSS changes may come into effect as negotiated after the expiry of the 7CPA.

The Guild/PSA

- The Guild would no longer be the sole representative in Commonwealth price negotiations. The PBRT would announce a public inquiry into the determination of the Commonwealth price and consider any submissions from interested parties in making their determination on the most appropriate Commonwealth price.
- Wholesale mark-ups, CSO and potentially NDSS distribution fees would be subject to negotiations between the Commonwealth and NPSA, as a representative of pharmaceutical wholesalers rather than with the Guild as has previously been the case in previous CPAs.
- PSA may continue to be responsible for development and maintenance of the Code of Ethics, professional standards and guidelines for pharmacists, subject to securing appropriate funding for these activities.
- CPPs would be reviewed to establish more robust data collection protocols which would inform future evaluation and future considerations to changes in scope and eligibility through normal policy development processes. There would be no requirement to obtain agreement to such changes from the Guild
 - Consultation and agreement on programs to be funded or added would be widened to include a broader range of stakeholders including consumer representative organisations, not just the Guild.

Services Australia and Pharmacy Programs Administrator (PPA)

- There would be no change to business operations for Services Australia which would continue to process and pay PBS dispensing claims from community pharmacies based on the remuneration of dispensing PBS medicines at the end to the 7CPA.

⁶³ <https://ajp.com.au/in-depth/business-class/the-high-road-or-the-low-road/> , <https://ajp.com.au/in-depth/business-class/the-valuation-impact/>

- The current arrangements with the PPA, where the Commonwealth pays the PPA to act as the administrator of the CPP to ensure compliance of pharmacies with the requirements of each individual program and to pay claims for services supplied, may change over time, depending on any changes to the administration and structure of CPPs.

Pharmacy wholesalers

- Pharmaceutical wholesalers maintain distribution facilities for medicines and are the link between sponsors of medicines and community pharmacies where the medicines are dispensed to people. Under the CSO wholesalers are required to ensure fast (generally within 24 hours but up to 72 hours) delivery of PBS medicines to community pharmacies irrespective of their location across Australia.
- NPSA, as the peak body representing wholesalers, and other significant pharmaceutical wholesaler groups not represented by the NPSA would be responsible for negotiating an initial position on wholesaler mark-ups in the absence of a CPA.
- CSO and NDSS arrangements may need to be separately negotiated with NPSA.
- No change to required stocking levels would be expected through these changes.

Option 2: Establish an 8CPA that includes all existing pharmacy programs

Under this option the majority of the functions, programs and services provided for under the 7CPA would remain unchanged, with negotiation of dispensing remuneration being the primary focus.

This option uses a well-established approach, and would continue to consolidate the funding for community pharmacy with respect to dispensing remuneration and funding of related professional pharmacy programs and services.

- While some changes to provisions included under the 7CPA may be up for negotiation, to update them for the next 5 years, the main focus would be updating the Commonwealth price.
- Dispensing remuneration would be increased by CPI with a real growth factor of 2.1%.
- No significant restructure of the functions, programs and services within the 8CPA would be included in this option.

Stakeholder roles and responsibilities

Consumers

- There would be no significant changes to existing processes, programs or services with no resultant changes for the public.
- People would be expected to be able to access the same or similar services to those currently funded through the 7CPA.
- Patient contributions through under co-payment prescriptions would increase as a result of an increased Commonwealth price.
- CPPs would be expected to continue in their current form with minimal scope for reform or innovation.

Pharmacies

- Under this option, there would be no change to existing processes.
- Community pharmacies would receive a continuation of revenue from the dispensing fees associated with the supply of PBS medicines to consumers. These fees would continue to be established and indexed through terms negotiated and agreed between signatories.
 - Payment would continue through Services Australia as currently provided.
- CPPs would continue largely as currently included in the 7CPA. This would limit potential reform while the 8CPA was in place as was the case under the 7CPA.

The Guild/PSA

- Whereas the Guild would continue to negotiate the sections of the CPA dealing with pharmacy dispensing remuneration and CPP, as in the 7CPA, PSA may continue to take a more active role in these negotiations. Negotiation of wholesale mark-ups, CSO Funding Pool and NDSS product distribution arrangements would also likely include the involvement of pharmaceutical wholesaler representative groups such as NPSA.
- PSA would continue to be responsible for development and maintenance of the Code of Ethics, professional standards and guidelines for pharmacists.
- Governance arrangements would remain the same or be improved through review of the current arrangements under the 7CPA.

Government

- This option provides the least flexibility in relation to CPPs.
- There would be no change to the existing process, with the change for Government primarily related to any financial change resulting from new dispensing remuneration negotiated through a new CPA.
 - Government would continue to pay pharmacies handling fees for the dispensing of PBS medicines.
 - Pharmaceutical wholesalers would continue to be paid to hold PBS medicines to ensure timely and efficient distribution of PBS medicines to community pharmacies.

Services Australia and PPA

- There would be no change to business as usual processes for Services Australia which would continue to process PBS dispensing claims.
- The current arrangements with the PPA, including funding, would likely continue for the administration, processing and payment of claims for the CPP.

Pharmacy wholesalers

- CSO and NDSS funding would continue to be included in the 8CPA, even if separately negotiated with representatives of pharmaceutical wholesalers.
- Pharmaceutical wholesalers would not be required to change current required stock levels.
- The NPSA would be included in negotiating any updated wholesale mark-ups, CSO and NDSS.

Option 3: Establish an 8CPA for dispensing remuneration and only pharmacy programs delivered directly through community pharmacies

The Government would seek to advance reforms reflecting a modern regulatory and policy environment to underpin the Australian medicine supply chain by reforming the structure of the CPA, and who the signatories and stewards are of specific components. The Commonwealth would enter into an 8CPA with the Guild on the Commonwealth price, to meet the requirements under Section 98BAA of the Act as well as those CPPs that are delivered directly through community pharmacies. The CPPs to be included in the 8CPA would comprise:

- MedsCheck
- Diabetes MedsCheck
- Staged Supply
- Dose Administration Aids (DAA)
- Indigenous Dose Administration Aids (IDAA), and
- Regional Pharmacy Maintenance Allowance (RPMA).

The agreement would include a requirement for the Guild to work with the Department to develop and implement an evaluation framework into the existing programs. The CPPs included in the agreement would be evaluated against the evaluation framework during the life of the agreement to inform any changes that may be required to better align the programs to deliver better clinical outcomes and accessibility to consumers who would gain the most benefit from the programs.

Separate discussions and agreements could then occur outside of the 8CPA timeframes with a range of stakeholders, including:

- Wholesalers (likely represented by the NPSA and non-NPSA wholesalers) on the CSO service requirements, and potentially amendments to the wholesale mark-up
- First Nations Health stakeholders (such as National Aboriginal Community Controlled Health Organisation (NACCHO)) on targeted First Nations Pharmacy Programs centred around Closing the Gap targets, and
- Professional pharmacy organisations (including the PSA) on all other professional pharmacy programs that are focussed on making community pharmacies an accessible health-hub for all Australians.

Any reforms such as those outlined above will include the collection of data, including in relation to health outcomes, to provide stronger evidence to guide future program development. Programs, including those included in the 8CPA would be structured to have quality and evaluation framework intrinsic in their design. These frameworks would be developed in consultation with relevant stakeholders to ensure that they were practical, efficient and fit for purpose.

With the NMP at its core, the 8CPA will also take into account the recommendations of prior reviews into the community pharmacy sector, including:

- The Competition Policy Review (Harper Review, 2015)⁶⁴
- Review of Pharmacy Remuneration and Regulation (King Review, 2018)⁶⁵
- Senate Select Committee on Red Tape: Effect of Red Tape on Pharmacy Rules (2018)⁶⁶, and
- The 5-Year Productivity Reviews by the Productivity Commission (2017⁶⁷, 2023⁶⁸)

Creating an effective regulatory and policy environment that is structured around the interests of the Australian people in accessing medicines and services through pharmacies would underpin the negotiation process.

Stakeholder roles and responsibilities

Consumers

- The Australian people would maintain access to PBS medicines as per previous CPAs.
- Patient contributions through under co-payment prescriptions may be reduced through negotiations for a new agreement, or would otherwise increase in line with indexation arrangements as set out in the National Health Act, and in line with any negotiated increases to the Commonwealth price.
- CPPs would continue to be delivered through community pharmacies but evaluation frameworks would be established to ensure the data required to inform better targeted eligibility and funding are collected to improve future patient access and outcomes.
- Consumers would have more input into the evaluation of CPPs through representation by consumer organisations and transparency would likely be improved.

Pharmacies

- Community pharmacies receive revenue from the dispensing fees associated with the supply of PBS medicines to consumers. These fees would continue to be established and indexed through terms negotiated and agreed between signatories, including the Guild.
 - Payment would continue through Services Australia as currently provided.
- Pharmacists could have more input into the structure, scope and design of CPPs.
- Administration and claiming processes for CPPs may undergo significant change and there would likely be some opportunity for reform of CPPs.

The Guild/PSA

- The Guild would continue to negotiate the sections of the Agreement dealing with pharmacy dispensing remuneration and CPP.
- PSA would continue to be responsible for development and maintenance of the Code of Ethics, professional standards and guidelines for pharmacists along with providing input into the evaluation of CPPs both in the CPA and those funded outside of the CPA.

Services Australia and PPA

⁶⁴ <https://treasury.gov.au/publication/p2015-cpr-final-report>

⁶⁵ https://apo.org.au/sites/default/files/resource-files/2018-05/apo-nid143826_1.pdf

⁶⁶ https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Red_Tape/Policyandprocess/~/_media/Committees/redtape_ctte/Policyandprocess/report.pdf

⁶⁷ <https://www.pc.gov.au/inquiries/completed/productivity-review/report/productivity-review-supporting-all.pdf>

⁶⁸ <https://www.pc.gov.au/inquiries/completed/productivity/report/productivity-advancing-prosperity-all-volumes.pdf>

- There would be no change to business operations for Services Australia for continuing to process and pay PBS dispensing claims from community pharmacies, although there may be business changes for new payments or changes to payment timeframes if negotiated through the new agreement.
- The current arrangements with the PPA as the administrator of CPPs including funding, may change over time, depending on any changes to the CPP.

Pharmacy wholesalers

- Negotiation of wholesale mark-ups, CSO Funding Pool and NDSS product distribution arrangements would occur through separate negotiations for an arrangement with pharmaceutical wholesaler representative groups such as NPSA.
- Other significant pharmaceutical wholesaler groups not represented by the NPSA may also be involved in negotiating an agreement with wholesalers including CSO arrangements. This would need to be integrated into the final Commonwealth price legislative instrument.
- No change to required PBS stocking levels would be expected through this change.

4. What is the likely net benefit of each option?

The net benefit for each option has been determined below by considering the extent to which each responds to the previously outlined objectives. Following this analysis, in order to allow clearer comparison overall, the scoring system below has been applied across each objective and option in Table 14:

1. Not at all
2. Somewhat
3. Mostly
4. Fully

In many instances the differences in impacts between options are likely to be small as each option is intended to achieve the core requirement of establishing an appropriate Commonwealth price for the dispensing of PBS medicines by pharmacies. A greater difference between Options exists however in relation to CPPs.

4.1 Person-Centred

The provision of dispensing remuneration supports the objective of enabling consumers to access timely and easy-to-understand information on the safe use of PBS medicines by ensuring that pharmacists when dispensing medicines are able to undertake the relevant checks, and consult with patients when required. This is consistent with the core role of a dispensing pharmacist and achieved across all options. Dispensing remuneration and the relative differences between options is covered further under the objective of equitable, sustainable and timely access below.

A number of CPPs also support a consumer focus in maximising the benefits from the use of prescribed medicines. Existing CPPs that focus on patient services (such as medication management and review programs), are funded on an ongoing basis.

In the absence of a CPA, as would apply under Option 1, these programs would continue in their current form in the short term, and their reviews prioritised and considered following the expiry of the 7CPA. This could result in expanded opportunities for the consideration and development of CPPs in consultation with a broad range of stakeholders including consumers and consumer representative groups.

Option 2 would continue to see existing CPPs outlined in an 8CPA including those that support the delivery of consumer-focused pharmacy programs and related services. These programs have continued to be improved and reprioritised under the 7CPA with a focus on being simplified for pharmacists and increasing the number of services for patients. While the number of services provided under the pharmacy programs has continued to grow, with year on year increases in expenditure, under the 7CPA as outlined in the Table 11 below, Option 2 would not provide the opportunity for significant CPP reform and the development of better targeted CPPs, through development with a broad range of stakeholders.

Table 11. Expenditure and number of services for consumer focused Community Pharmacy Programs under the 7CPA

Program or Service	July 2020– June 2021			July 2021 – June 2022			July 2022- June 2023		
	No. Providers ^a	Total Services	Expenditure	No. Providers	Total Services	Expenditure	No. Providers	Total Services	Expenditure
Dose Administration Aids	4,989	15,752,222	\$97,432,020	5,034	15,846,601	\$98,167,717	5,034	16,210,288	\$100,337,959
Indigenous Dose Administration Aids*	n/a	n/a	n/a	1,827	1,477,949	\$17,467,454	2,157	1,878,629	\$22,060,207
Staged Supply	2,635	184,360	\$8,835,567	2,642	188,774	\$9,051,710	2,933	200,820	\$9,280,680
HMR**	1,351	119,420	\$23,858,714	1,211	118,960	\$22,764,443	1,306	144,498	\$27,330,666
RMMR**	192	129,269	\$13,189,034	188	146,430	\$14,557,878	178	155,885	\$15,321,390
MedsCheck	3,251 ^b	402,552	\$26,781,803	3,258 ^b	389,190	\$25,892,811	3,622 ^b	423,450	\$28,172,133
Diabetes MedsCheck	3,251 ^b	136,536	\$13,625,041	3,258 ^b	148,530	\$14,821,809	3,622 ^b	193,475	\$19,306,887
Quality Use of Medicines in Residential Aged Care Facilities	190	2,951 ^c	\$11,084,434	192	2,905 ^c	\$11,483,595	166	2,699 ^c	\$11,482,520

* The Indigenous Dose Administration Aids program commenced on 1 July 2021

** Total services for Home Medicines Review (HMR) and Residential Medication Management Review (RMMR) programs are inclusive of services paid for first and second follow up.

a - This item reports the maximum number of participating service providers for this service in any one month during the reporting period. The total number of service providers is not cumulative. A service provider is considered 'active' if they submitted a claim in relation to the program during the month

b – Indicates the maximum number of participating Service Providers for MedsCheck & Diabetes MedsCheck, in any one month during the reporting period.

c – This item reports the maximum number of facilities participating receiving a QUM service in any one month during the reporting period. Please note that it does not represent the number of services provided.

Information sourced from [Community Pharmacy Programs data](#) published by the Department of Health and Aged Care.

Option 3 would focus an 8CPA on dispensing remuneration, and those CPPs delivered through community pharmacy, with the remaining CPPs, which may be provided by community pharmacies or in other types of settings, to be considered outside of the CPA process. This approach would allow for greater stakeholder collaboration by broadening the stewards of relevant programs and services, and ensuring the views of a wider range of stakeholders, including consumer input, informs the development of relevant policy and programs. As with Option 1 existing CPPs could be continued as is until they were formally evaluated and actions taken to ensure they are delivering on intended outcomes. This approach provides greater flexibility for programs outside of the CPA removing the need to renegotiate arrangements within the 8CPA agreement timeframes and allowing for a more robust consideration in collaboration with a range of stakeholders outside of this process.

Option 3 aligns with stakeholder feedback throughout consultations which suggested there is an opportunity to consider the establishment of pharmacy programs targeted at specific populations, such as additions to the Indigenous Pharmacy Programs (IPPs). Separation of CPPs from the CPA allows for smaller, more patient centric, programs which are tailored specifically to the requirements of specific patient cohorts. It also provides scope for more robust consideration of the best mechanisms for delivery each service.

Option 3 is also most consistent with recommendations from successive reviews and inquiries into aspects of community pharmacy restrictions and remuneration including the 2018 Senate Select Committee on Red Tape: Effect of Red Tape on Pharmacy Rules⁶⁹ and the Review of Pharmacy Remuneration and Regulation's Final Report⁷⁰ which stated:

“To reduce the complexity of future CPAs, the scope of agreements should also be limited to remuneration for dispensing. This means not including wholesaling or other professional programs offered by community pharmacies. Rather, these should be negotiated and agreed separately.”

Continuing to include the CPPs delivered through community pharmacy in the CPA, would however consolidate considerations of the funding arrangements for community pharmacies and simplify the extension of existing arrangements. This, however, requires careful future management, to ensure that the same levels of rigorous evaluation and assessment are applied across all programs that support medicine-related services for Australians, to ensure that optimal health outcomes are achieved.

4.2 Equity, sustainability and Access for Consumers

The dispensing of PBS subsidised medicines through community pharmacies is a key component of supporting safe and reliable consumer access to medicines for all Australians. The 7CPA has continued to support effective and efficient access to PBS medicines to the community with increasing prescription volumes following its commencement. Over the first three years of the 7CPA from 2020-23 the actual

⁶⁹ [https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Red_Tape/Policyandprocess/~media/Committees/redtape_ctte/Policyandprocess/report.pdf](https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Red_Tape/Policyandprocess/~/media/Committees/redtape_ctte/Policyandprocess/report.pdf)

⁷⁰ https://apo.org.au/sites/default/files/resource-files/2018-05/apo-nid143826_1.pdf

subsidised script volumes, and resulting dispensing remuneration, has been higher than the original 7CPA estimates.

Recent changes to policy settings outside of the CPA, for example, 60-day dispensing, are expected to result in reductions over the forward estimates. The revised 7CPA estimates in Table 12 below reflect the trend in recent actual volumes as well as current policy settings (e.g. general co-payment reduction, safety net threshold reduction and 60-day dispensing/MDQ). Note that volume forecasts do not include new and amended listings that will result from future PBAC consideration.

Table 12. Volumes of PBS medicines dispensed (million)

	2020-21 Actual	2021-22 Actual	2022-23 Actual	2023-24 Forecast	2024-25 Forecast	5-year Total
Over co-payment (Subsidised) Prescriptions	214.9	215.1	223.1	222.3	201.7	1,077.1
Under co-payment (Unsubsidised) Prescriptions	92.0	100.8	105.7	101.5	92.2	492.2
Total Prescriptions	306.9	315.9	328.7	323.8	293.9	1,569.2

While the volume of medicines dispensed wouldn't be anticipated to change between options the patient contributions through co-payments would differ slightly with changes to the Commonwealth price, and could change further depending on whether reforms are negotiated in a new agreement to address current cost of living concerns. The estimated patient contributions for Options 2 and 3 are outlined below. The estimated patient contributions under 7CPA across 5 years are also provided in Table 13 as a comparison, although it isn't possible to provide an estimate for Option 1 as the Commonwealth price would be established by the independent PBRT after the expiry of the 7CPA.

Table 13. Comparative patient contribution estimates over 5 years

Components of remuneration	7CPA (\$billion)	Option 2 8CPA (\$billion)	Option 3 8CPA (\$billion)
Dispensing remuneration – Under co-payment (Unsubsidised) (patient contributions)	\$6.4	\$8.1	\$6.7

The primary disadvantage of Option 1 is the lack of certainty it provides and the impact that this may have on both consumers and the pharmacy sector as a whole. The timeframes for the completion of a PBRT determination are unstipulated and unable to be estimated. In addition, while the outcomes are also unknown, the continued growth in the number of approved pharmacists, and sector reporting of increasing profits over recent years⁷¹, means it is possible an independent assessment of the cost of dispensing by the PBRT could result in reduced dispensing remuneration per script and overall.

If community pharmacies were not able to negotiate what they consider to be a fair price this could result in pharmacy closures and therefore reduced access to medicines and health care offered through pharmacies, particularly in rural and remote areas where there is often only one pharmacy within a community. Pharmacy closures in regional and remote areas in particular can result in community

⁷¹ <https://www.uts.edu.au/sites/default/files/2022-05/GSH-Pharmacy-Barometer-2021.pdf>

members having to travel significantly further to access medicines and pharmacy services. This can further impact individual health, and the health system more broadly, as people may wait longer to seek advice or treatment in relation to minor ailments which may then escalate into more clinically significant issues.

Option 2 would see the establishment of an 8CPA that is similar in scope and approach to the 7CPA which commenced on 1 July 2020 and was intended to operate until 30 June 2025. Consumer access to PBS medicines and other pharmacy services under this option would therefore remain unchanged (subject to reforms negotiated as part of an agreement).

Option 3 would also continue to see dispensing remuneration outlined in an 8CPA, which would provide certainty to consumers and pharmacy owners. Consumer access to PBS medicines and other pharmacy services under this option would therefore also largely remain unchanged (subject to reforms negotiated as part of an agreement).

4.3 Equity, sustainability and Access for Businesses

Businesses are most directly affected by the Commonwealth price. Option 1 would see the Commonwealth price independently determined by the PBRT, following the 7CPA expiry on 30 June 2025. The Commonwealth price in effect at the expiry of the 7CPA would continue at the level set at the end of the 7CPA until the PBRT could make an independent determination, following a public consultation process. The PBRT would also independently determine the frequency with which pharmacy remuneration was to be reviewed and determined.

The PBRT review would not extend to consideration of remuneration for pharmacy programs or services. Separate arrangements for critical services, including CSO and NDSS product distribution, would therefore need to be negotiated and implemented as soon as possible after the termination of the 7CPA to ensure that the availability and distribution of PBS medicines and diabetes self-management products was not disrupted.

Under Option 1 the Department would need to put arrangements in place to consider the RPMA, and other programs which help to support pharmacies in more rural and remote locations. The RPMA arrangements are currently only partly funded outside of the 7CPA. This may further affect those pharmacies in rural and remote communities. While it may be possible to put arrangements in place to ensure the continuation of the full scope of this allowance in the short term this transition would not be straightforward and re-review following a PBRT determination would likely be required, resulting in a further uncertainty.

The average dispensing remuneration per script under Option 2 will grow each year in line with CPI plus an additional 2.1% of real growth, from the current (2023-24) \$13.11 to an estimated \$19.81 in the last year of the 8CPA (2028-29).

Option 3 would focus an 8CPA on dispensing remuneration and CPPs delivered in community pharmacies. This approach would provide certainty to businesses and allow for CSO and wholesaler arrangements to be negotiated directly with wholesalers (likely represented by the NPSA and non-NPSA

wholesalers) outside of the CPA. The average dispensing remuneration per script will grow each year in line with CPI as per the 7CPA from the current (2023-24) \$13.11 to \$17.60 in the last year of the 8CPA (2028-29). The total dispensing remuneration over 5 years would be anticipated to increase only slightly from that of the 7CPA, because of the lower prescription volumes anticipated as discussed under the objective above.

Table 14 below outlines the estimated actual expenditure under a five year 7CPA from 2020-21 until 2024-25 in addition to the indicative maximum allocations under a five year 8CPA under Options 2 and 3. Estimates of possible change to the funding model under Option 1 have not been made so as not to compromise or pre-empt the findings of the independent PBRT.

Table 14. Comparative dispensing remuneration funding under 7CPA and 8CPA under Options 2 and 3

Components of remuneration	7CPA (\$billion)	Option 2 8CPA (\$billion)	Option 3 8CPA (\$billion)
Dispensing remuneration – Over co-payment (Subsidised)	\$14.8	\$19.3	\$17.9
Dispensing remuneration – Under co-payment (Unsubsidised)	\$6.2	\$8.1	\$6.7
Total remuneration for dispensing (excluding wholesaler mark-up)	\$20.9	\$27.4	\$24.6

4.4 Accountability and Transparency

Consumers are understandably more concerned about transparency of the components of price they pay for medicines than the Commonwealth price for dispensing. In recognition of this the 7CPA requires that there be increased transparency and information to patients about the cost of medicines (including any discretionary pharmacy charge), prior to the medicine being dispensed to the patient. Consistent with this requirement the Guild developed information and resources for use by community pharmacies and consumers to better understand the pricing and costs of a PBS prescription and made these available on its website (www.findapharmacy.com/pbs-pricing) from February 2022.

Many stakeholders however felt that, these resources fail to inform consumers of the costs of their medicines prior to being dispensed and do not address genuine concerns of consumers about costs and the quality of information being provided by pharmacies. Some also considered that discussions regarding further improvements had been constrained by the wording of the 7CPA and further questioned the appropriateness of messaging, suggesting there needs to be wider consideration of health literacy issues and increasing patient access to reputable information sources regarding medicines in varying formats.

Under Option 1 the Commonwealth price would be set by PBRT following a public inquiry. This would open up the process of setting the general level of remuneration for dispensing medicines for public scrutiny but would not improve transparency of individual costs at the point of dispensing.

Option 2 would see the establishment of an 8CPA similar in scope and approach to the 7CPA. Transparency of charges undertakings as outlined in the 7CPA would be maintained but would be unlikely to result in any significant improvement or change in transparency of charges.

Option 3 would focus an 8CPA on dispensing remuneration, and may provide an opportunity for broader discussion outside of the CPA about how transparency and understanding of PBS medicine costs could be improved with a range of stakeholders.

4.5 Innovation and Continuous Improvement

There are more than 20 existing CPPs that focus on three key areas: medication management and adherence programs, rural support programs and First Nations specific programs. Most stakeholders are supportive of separating CPPs from the CPA (see section 5 below) noting that this would encourage innovation and the continued improvement of the pharmacy sector.

Option 1 could provide expanded opportunities for the consideration of CPPs and support the development of program quality and evaluation frameworks which would allow for better analysis of associated health and cost benefits. However, there is risk that due to sector uncertainty during the PBRT inquiry period that stakeholders may be less willing to engage in relation to additional activities including pharmacy programs.

Existing CPPs that focus on patient services (such as medication management and review programs), are ongoing and demand driven. These programs would continue in their current form in the short term, and their reviews would be prioritised and considered following the expiry of the 7CPA. As there would be no restrictions on timeframes due to a CPA agreement being in place, extensive collaboration with stakeholders could be undertaken. Consultations would include consideration of the scope of each of the existing CPPs separately and enable the opportunity to develop quality and evaluation frameworks for these programs.

Option 2 would provide limited opportunity for CPP reform as funding for existing CPPs would see them continue to be outlined in an 8CPA with minimal changes. The Department would however seek to establish evaluation frameworks in consultation with stakeholders following the commencement of the 8CPA, noting that this may be more difficult to achieve once an agreement is already in place.

Option 3 would see only pharmacy programs delivered directly through community pharmacies included in an 8CPA which would include a commitment to the establishment of a corresponding quality and evaluation framework for each of these programs. This would include the appropriate collection of health outcome data to further inform future program development and better inform the extent to which the objectives of each program have been met. This approach would also allow for the implementation of separate pharmacy program and services arrangements in relation to the other CPPs.

A summary of the overall net benefit for each objective is presented in Table 15.

Table 15. Net benefit analysis of each option

Objective	Option 1	Option 2	Option 3
Person-Centred Dispensing: Consumers are able to access detailed, timely and	Fully (4) Remuneration for dispensing should continue to support pharmacist consultation with	Fully (4) Remuneration for dispensing should continue to support pharmacist consultation with	Fully (4) Remuneration for dispensing should continue to support pharmacist consultation with

easy-to-understand information on the safe use of PBS medicines.	the person receiving the dispensed medicine. This includes providing drug safety and care instructions for the recipient.	the person receiving the dispensed medicine. This includes providing drug safety and care instructions for the recipient.	the person receiving the dispensed medicine. This includes providing drug safety and care instructions for the recipient.
Person-Centred Programs: Consumers and consumer perspectives inform the design of CPPs and further enhance health and medical literacy.	Somewhat (2) Provides an opportunity for the development of better targeted CPPs through extensive consultation with consumer groups and a broader range of stakeholders. However pharmacy stakeholders may be less willing to engage in program design until after a PBRT decision is made due to a lack of certainty over future dispensing remuneration.	Not at all (1) All existing CPPs would continue to be negotiated within the CPA without direct input from consumers or consumer groups.	Fully (4) Evaluation frameworks would be established for all CPPs in the CPA and inform consideration of future changes to improve patient outcomes. Input from consumers and consumer groups would be incorporated into the design and evaluation of CPPs to ensure they are better targeted to meet the needs of consumers. CPPs outside of the CPA would also be reviewed.
Equity, sustainability and Access for Consumers Consumers can access PBS medicines in a timely manner irrespective of their geographical location.	Somewhat (2) There would a degree of uncertainty around future of pharmacies, which may lead to consumer concern and reduced access in some areas.	Fully (4) Equity and access for consumers to PBS medicines and other pharmacy services would largely remain unchanged.	Fully (4) Equity and access for consumers to PBS medicines and pharmacy other services would largely remain unchanged.
Equity, sustainability and Access for Businesses Provides for timely supply of PBS medicines irrespective of geographical location and supports pharmacy viability, particularly in rural and remote areas.	Somewhat (2) There would a degree of uncertainty around future of pharmacies, wholesaler and CSO arrangements. May be an opportunity for CPPs supporting rural and remote pharmacies to be negotiated with a broad range of relevant stakeholders. However pharmacy stakeholders may be less willing to engage in program design until after a PBRT decision is made.	Mostly (3) Wholesaler and CSO arrangements would remain unchanged. CPPs supporting rural and remote pharmacies would largely remain unchanged with limited opportunities for stakeholders to participate in the evaluation and restructure of programs. Dispensing remuneration would be set at a level that would maintain business confidence in community pharmacy.	Fully (4) Wholesaler and CSO arrangements would be negotiated directly with the relevant stakeholders outside of the CPA. CPPs supporting rural and remote pharmacy workforce would be negotiated outside of the CPA with a broad range of relevant stakeholders. This could provide for better targeted support with more flexible timeframes for the design and implementation of improvements.

			Dispensing remuneration would be set at a level that would maintain business confidence in community pharmacy.
Accountability and Transparency Consumers are able to access through their pharmacy easy-to-understand information on the costs they will incur in accessing PBS medicines and potential differences between pharmacies.	Fully (4) Commonwealth price would be set by PBRT with a public inquiry. This would open up the process of setting the general level of remuneration for dispensing medicines for public scrutiny.	Somewhat (2) The CPA outlining Commonwealth price would be published. Transparency of charges clauses as outlined in the 7CPA would be maintained with a requirement for the Guild to publish cost breakdowns online and use their best endeavours to ensure pharmacies explained to consumers details of fees and charges applicable.	Mostly (3) The CPA outlining Commonwealth price would be published. Transparency would be further strengthened building on work in the undertaken through the 7CPA.
Innovation and Continuous Improvement Supports the collection and evaluation of evidence/data on the impact pharmacy services have on health outcomes.	Somewhat (2) Provides an opportunity for the development of better targeted CPPs which are supported by evaluation frameworks. However pharmacy stakeholders may be less willing to engage in program design and evaluation until after a PBRT decision is made.	Not at all (1) Existing programs would continue unchanged.	Fully (4) Evaluation frameworks would be developed to support the evaluation of health outcomes and cost effectiveness of each program in the 8CPA and drive innovation within the pharmacy sector. CPPs supporting pharmacists, pharmacy workforce and First Nations health would be negotiated outside of the CPA with a broad range of relevant stakeholders. This could provide for better targeted support with more flexible timeframes for the design and implementation of improvements.
Total Score (24 max)	16	15	23

4.6 Regulatory Burden estimates

The regulatory effort required by stakeholders remains the same irrespective of the price point for dispensing set in the CPA. Systems and processes for administering the remuneration (through Services Australia and the PPA) are well established and no change in administration is required where a simple change in remuneration is made. Therefore the change in regulatory burden is considered nil (or negligible) where only a price has been renegotiated.

Regulatory burden may occur where there are changes to the scope of the CPA as a result of the up-front requirement (or possible requirement) for businesses and community organisations to contribute to the development of pharmacy programs and services outside of the CPA to secure ongoing program funding. Beyond this initial additional regulatory burden, the reporting requirements are considered the same as those for the 7CPA. An outline of the assumptions used to consider this burden across all options is provided at Appendix 6.

Option 1 would see the separate negotiation of both wholesaler funding arrangements and pharmacy program funding and the implementation of evaluation frameworks. This would create a small additional impact on the pharmacy sector and relevant community organisations who would contribute to the development and agreement of these arrangements and their evaluation frameworks as outlined below. Impacts of any new arrangements would be considered separately as these individual proposals were developed in the future.

A full regulatory burden table for Option 1 isn't possible as this would be heavily dependent on the outcomes of the independent assessment of the PBRT. The timeframes for the PBRT to complete a determination assessment are unknown, but assessment could not begin until after the expiry of 7CPA on 30 June 2025. Until this time, the 7CPA would remain in place with the following impacts.

Regulatory burden estimate (RBE) table – Option 1 until 30 June 2025

Average annual regulatory costs				
Change in costs (\$ million)	Individuals	Business	Community organisations	Total change in cost
Total, by sector	\$0	\$0.088	\$0.011	\$0.099

Under Option 2 community pharmacists will be most directly affected by changes to pharmacy remuneration and publicly funded pharmacy programs. The changes to pharmacy dispensing remuneration, wholesaler mark-up and supply funding under this option would however be small and align with the broad approach taken in 7CPA. There would be no change in regulatory activities undertaken or dispensing services delivered by pharmacist and no impact on individuals.

In addition this option would see the continuation of existing programs, with further consideration given to the implementation of program evaluation frameworks to occur separately following the commencement of 8CPA. If an evaluation framework was separately implemented this could have a regulatory impact but this has not been modelled as there are as yet no parameters on what such a framework would take and would be considered at a future time. The costing of regulatory burden for Option 2 is for the proposed life of the new CPA, 5 years.

Regulatory burden estimate (RBE) table – Option 2

Average annual regulatory costs				
Change in costs (\$ million)	Individuals	Business	Community organisations	Total change in cost
Total, by sector	\$ 0	\$0	\$0	\$0

Despite the proposed changes to the Commonwealth price in relation to pharmacy dispensing remuneration and wholesaler mark-up funding under Option 3 these changes are in effect relatively small and would require no additional effort from pharmacists or individuals. There would be no change in regulatory activities undertaken or dispensing services delivered by pharmacies and no impact on individuals.

This option would also see the separate negotiation of program funding and implementation of evaluation frameworks. While the impacts of these programs would therefore be considered as separate policy proposals this will create an additional impact on the pharmacy sector and relevant community organisations who will contribute to the consideration, development and agreement of the programs and their evaluation frameworks. The costing of regulatory burden for Option 3 is for the proposed life of the new CPA, 5 years.

Regulatory burden estimate (RBE) table – Option 3

Average annual regulatory costs				
Change in costs (\$ million)	Individuals	Business	Community organisations	Total change in cost
Total, by sector	\$0	\$0.087	\$0.012	\$0.099

5. Who will you consult about these options and how will you consult them?

On 7 August 2023, the Minister for Health and Aged Care, the Hon Mark Butler MP, announced an early negotiation for an 8CPA.⁷² In his announcement the Minister stated that the Department would begin consultation with a broad range of stakeholders including patient groups, medicines wholesalers and distributors, and others who have an interest in the growth and development of pharmacy services that benefit all Australians in addition to the signatories of the 7CPA, the Guild and PSA. Given the commercial and financial sensitivities associated with this policy proposal, consultation was undertaken in a confidential manner.

The Department viewed broad-based consultation with a variety of stakeholders to be a critical component of the negotiations. A number of Government-commissioned Independent Reviews have recommended that “the range of stakeholders included for consultation would represent those who deliver on the agreed services” in order to “improve the overall transparency and sustainability of the sector”.⁷³ Further, it noted that previous CPAs have had their implementation activities actively “hampered by a lack of adequate stakeholder engagement and lack of communication on progress”.⁷⁴ As such, the Department has prioritised consultation with a broad range of stakeholders as a foundational element of a successful 8CPA. This work has translated into directly informing Government priorities on issues such as a potential wholesaler agreement, the operation of some community pharmacy programs outside of the 8CPA policy setting and the development of evaluation frameworks for all pharmacy programs both within and outside of the 8CPA.

The confidential nature of negotiations and legislated requirement for agreement with the Guild limits the approach to stakeholder consultations, with non-disclosure agreements in place for all parties involved in relevant discussions. A further limitation to consultations is the timeframes available. Together these limitations have meant that, while weekly meetings were held with the Guild and fortnightly meetings with PSA, the Department was only able to meet with some stakeholders once. This challenge could be overcome in future by allowing more time for negotiations, noting that negotiations would typically begin at least 12 months ahead of the expiry of a CPA.

The Department however sought bilateral meetings with as wide a range of stakeholders as was practical to cover the myriad of interested parties and affected groups. A strong focus was on organisations with consumer interests at the forefront of their remit, along with organisations focused on rural and remote pharmacy services.

Following the Minister’s announcement the Department met with the following organisations for without prejudice, bilateral consultations:

Aged & Community Care Providers Association (ACCPA)

⁷² <https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/negotiations-for-an-eighth-community-pharmacy-agreement?language=en>

⁷³ https://www.apo.org.au/sites/default/files/resource-files/2018-05/apo-nid143826_1.pdf

⁷⁴ <https://www.oia.pmc.gov.au/sites/default/files/posts/2023/01/Post-Implementation%20Review%20of%20the%207CPA.pdf>

Australian Council of Social Service
Australian Friendly Societies Pharmacies Association Ltd
Australian Medical Association (AMA)
Australian Patients Association
Australian Rural Health Education Network
Chemist Warehouse Group (CWH)
Consumers Health Forum of Australia (CHF)
Credentialed Pharmacist Association of Australia
DHL Supply Chain
Embedded Health Solutions
Generic and Biosimilar Medicines Association
National Aboriginal Community Controlled Health Organisation (NACCHO)
National Pharmaceutical Services Association (NPSA)
National Rural Health Alliance
Painaustralia
Pharmaceutical Society of Australia (PSA)
The Pharmacy Guild of Australia
Professional Pharmacists Australia (PPA) (known as Professional Australia)
Royal Australian College of General Practitioners (RACGP)
Rural Pharmacy Network Australia (RPNA)
Society of Hospital Pharmacists of Australia (SHPA)

In each of the initial bilateral discussions participants were asked to provide input on what they would like to see included in an 8CPA, as well as provide more general input on how the agreement could potentially be restructured to better reflect current and future needs of the sector and ensure a person-centred approach.

The core questions posed by the Department in discussions with each organisation were as follows:

1. How could an 8CPA put patients at its core? What needs to change from current arrangements?
2. Are there any changes you wish to see to the structure of the CPA and if so why?
3. Are there any changes you would like to see to the content of the CPA and if so why?
4. Are there reforms you wish to see within the existing pool of funding for remuneration and/or programs?
5. What should the government stop paying for? Why?
6. What, for your organisation, should be the key focus of a new Agreement? Why?

Through bilateral discussions individual stakeholders were able to present their specific views and the confidential nature of these discussions may in many respects have encouraged greater input than group consultations. An exception to this may be the consumer focussed stakeholder groups as in multiple instances these groups noted to the Department that their preference would be to run consumer surveys prior to providing input.

Summary of feedback from consultations

There was strong agreement among most of the stakeholders that the 8CPA represented an opportunity to implement significant reform to the funding of community pharmacy by the Commonwealth government. There was broad agreement that reform should include comprehensive stakeholder engagement and consideration of the most appropriate scope of an 8CPA.

Within this context stakeholders generally presented the view that Commonwealth funding for both dispensing remuneration and CPPs should be increased and that dispensing remuneration should continue to be agreed through a CPA type arrangement.

There were multiple matters raised where there was conflicting input as to what should or shouldn't be included in any new agreement. On the matter of the optional \$1 discount allowing pharmacies to reduce the relevant co-payment amount, several stakeholders suggested that the value of the optional discount should be increased with one stakeholder suggesting that the discount could be to the entire value of the concessional co-payment. Another stakeholder however advocated for total abolition of the \$1 discount stating that because pharmacies do not universally apply the discount it was inequitable for patients.

There was wide ranging, but not universal, agreement that the current CPPs should be funded outside of the 8CPA and not tied specifically to community pharmacy. Stakeholders suggested this would allow for more robust consideration of the most appropriate providers, whether an independent consulting pharmacist, First Nations Health Service or community pharmacy, and funding arrangements for each program individually.

This perspective was also consistent with the similarly persistent, though not universal, view that the CPA should return to operating in a form closer to its initial legislated requirements; that being a mechanism for agreement on dispensing remuneration. The proposal under Option 3 to work towards a separate agreement for wholesalers is consistent with this position and is broadly supported by stakeholders from across the sector.

Many stakeholders also noted that the ongoing funding of existing CPPs should be tied to the establishment of and compliance with robust quality and evaluation frameworks. The need for reform in this space was universally acknowledged and desired by stakeholders.

Stakeholders also noted that patient benefits and quality use of medicines issues should be the primary focus of any program associated with pharmacy. It was recognised that monitoring of these impacts and program evaluation can only be assessed by collecting robust data in a manner that provides for broad comparisons through establishing agreed parameters to measure the benefit of each individual program.

A common theme was that funding for services should be linked to robust evaluation frameworks to ensure that the services were providing value for money and a clinical benefit to those receiving them.

Several stakeholders indicated that they would support First Nations pharmacy programs to be administered by First Nations organisations such as NACCHO. This was either through support of new programs or for all First Nations focussed pharmacy programs including existing workforce support and

pharmacy programs to be included in a single package to be administered by a single organisation. The rationale for this support was primarily that a First Nations-operated organisation would be best placed to tailor these programs to best meet the needs of First Nations peoples.

There was support for including structural change in any agreement to include supporting a model allowing for the separation of dispensing and non-dispensing pharmacists in the community health workforce. This could be enabled by supporting embedding non-dispensing pharmacists in healthcare providers such as primary care clinics and ACCHOs.

There was further limited support to explore funding for pharmacists to perform more clinical duties not coupled to dispensing revenue, especially within rural and remote pharmacies. Many of these pharmacies are small businesses with possibly only one pharmacist. Sometimes they are also the only medical service provider within the region. Support is therefore needed to enable other pharmacists to be employed in the pharmacy in order to allow for a broader scope of professional services such as medication adherence and medication review interventions to be offered to these communities.

There was significant stakeholder input suggesting the Home Medicine Review (HMR) program should be expanded, and consideration given to removing the cap of 30 reviews per month per service provider. The intent of the HMR Program is to support the quality use of medicines and assist minimising adverse medicine events by helping people to better understand and manage their medicines through a medication review conducted by an Accredited Pharmacist in the home. Feedback received from the bilateral meetings indicated that there was support for the HMR (and the associated Residential Medication Management Review (RMMR) program) to be de-coupled from community pharmacy to remove any possibility of conflict of interest for any recommended de-prescribing which would impact remuneration through loss of dispensing revenue. This de-coupling would enable GPs and specialist prescribers to refer patients who may be in need of a medicine review to consultant pharmacists directly.

In regards to MedsChecks and Diabetes MedsChecks (where a pharmacist provides one on one consultations in a pharmacy on all the medicines that a consumer is currently taking including non-prescribed medicines), several stakeholders voiced concerns that services conducted in a community pharmacy have limited clinical benefit to patients as there was no requirement to notify the patient's normal prescribers of any outcomes of the review. Stakeholders also noted that while the primary goal of the programs is to aid in improving the health literacy of patients in managing their own medicine compliance, there is very little evidence available to indicate that these interventions lead to better adherence by patients. It was also suggested that MedsChecks don't work well in rural and remote areas where pharmacists are often too busy with other work to perform them and the distance required to travel into a pharmacy is prohibitive.

There was extensive support to enable new pharmacy programs and support to allow for pharmacists to work to the top of scope of practise to be implemented. Specifics of how this could be implemented through an 8CPA or other arrangements were limited during the consultations.

Several stakeholders indicated that any new agreement should include mechanisms to improve the transition of care from hospital to either an aged care facility or to home. This would be open to consideration from any reform of CPPs through the preferred option.

In light of the stakeholder feedback Option 3 has been developed to explicitly focus on reform options both enabled within the auspices of the agreement for those relevant CPPs to be included within the CPA, and in a separate co-design process with all relevant parties for the remaining pharmacy programs.

Ongoing consultations

The Department will continue to work with community organisations, consumer organisations and pharmacy stakeholders, including the Guild and PSA, to review and consider the development and implementation of pharmacy programs and services. This would include the design of data collection and development of an evaluation framework for each program, to provide for the analysis of the health outcomes being achieved as well as the cost effectiveness of programs.

Through these consultations robust evaluation frameworks for the CPPs included in the 8CPA will be developed within 18 months. Within this timeframe data collection and analysis would occur to establish a baseline. Any changes that are recommended through the analysis of data collected through the evaluation frameworks would then be implemented as soon as possible or be used to deliver changes in the next round of negotiations for a 9CPA should the Government wish to enter a new agreement.

The Department is also continuing to engage with wholesaler stakeholders to negotiate the wholesaler arrangements. These consultations have been undertaken in parallel with the 8CPA negotiations and are expected to be concluded in 2024.

6. What is the best option from those you have considered and how will it be implemented?

Preferred option

To enable successful establishment of an appropriate Commonwealth price for the dispensing of PBS medicines, the preferred option is the option which will provide the greatest net benefit and achieve equitable, timely, safe and reliable access to medicines and pharmacy services at a cost that individuals and the community can afford. A summary of the net-benefit analysis of each of the three options is provided in Table 15 and identifies Option 3 as the preferred approach.

Looking at 'person-centred dispensing', the first criterion, it is clear that there is little variation between the options. This is because ensuring appropriate remuneration for dispensing activities remains core to each option and a certainty regardless of the final Option chosen.

'Person-centred programs' sees greater variation between options. Option 1, graded two (2) out of a potential four points, sees an opportunity for CPP reform through wider consultation than is currently possible, however it notes that the lack of certainty caused by transitioning to the PBRT for determining the Commonwealth price would inevitably have implications on participation by community pharmacists in these reforms. Option 2, does not provide any further opportunity for program reform, and so is scored a one (1). Finally, Option 3 was viewed as fully enabling a positive reform opportunity for CPPs going forward and achieved a full value of four (4).

The next criterion, 'equity, sustainability and access for consumers' sees identical full value (4) from Options 2 and 3, noting that dispensing remuneration would continue as expected in both Options. However, it notes that Option 1 would create uncertainty among community pharmacy as to how dispensing remuneration would operate. Due to this remuneration generally acting as the financial backbone of the community pharmacy, it would be likely that this uncertainty would have indirect implications for consumer access to community pharmacy across the country as the sector adjusted to an alternate form of remuneration. These considerations meant that Option 1 was given a value of two (2).

Similar results were found for Option 1 in the next criterion, 'equity, sustainability and access for businesses'. The uncertainty in financial arrangements, not just in remuneration but for all elements of the CPA, such as pharmacy programs, CSO and wholesaler arrangements and support for regional, rural and remote pharmacies, would be a significant challenge in the short-term. This uncertainty would likely have direct business implications for those in the sector. Option 2 sees the current funding mechanisms maintained, noting that wholesaler and CSO arrangements remain within the CPA, and would be unable to be reformed through alternative arrangements. As such, it is valued three (3), providing certainty but not reform opportunity. Option 3, was valued at four (4) as it gives business certainty going forward however it also opens up reform opportunities as negotiated during the finalisation of an agreement.

'Accountability and transparency' has a range of scores across the options. Option 1, which would place the responsibility of price setting upon the PBRT, was scored as a four (4). In this scenario, it was viewed

that the tribunal would open up the price-setting mechanism for the general level of remuneration, and improve the transparency of costs within the PBS. Option 2 would have an 8CPA published which includes the components which add up to the Commonwealth price. This would maintain the current situation, but would not significantly improve transparency of individual costs to consumers. As such, it was scored a two (2). Option 3 provides the clearest pathway for reform, as it also provides the justification for the Commonwealth price within the published 8CPA, but would additionally provide opportunity to continue to improve transparency and increase consumer understanding and awareness of PBS medicine costs both through relevant commitments in the 8CPA and related future stakeholder engagement. As such, it was scored higher than the other Options at a three (3).

Finally, ‘innovation and continuous improvement’ saw distinctly different outcomes and scoring between the three Options. Option 1 saw the opportunity for reform through the removal of the current CPA structures. However, this potential opportunity was mitigated somewhat by the uncertainty created by the removal of the existing funding structures. It noted that meaningful engagement from community pharmacists in reforming CPPs would be unlikely to occur until business confidence was restored. As such, it was scored a two (2). Option 2 saw no potential for changes to the current situation which has persisted across multiple CPAs, and it was therefore scored as a one (1). Option 3 introduced several avenues of meaningful reform potential, with some CPPs considered outside of the CPA as well as the establishment of independent wholesaler and CSO funding arrangements. Finally, Option 3 would establish a distinct evaluation reform agenda for CPPs. This would see an agreement between all key stakeholders to ensure that consultation continues to progress towards implementation of the evaluation frameworks planned for mid-2026. These benefits scored Option 3 full value of four (4) for this criterion.

Following consultation, and informed by the net-benefit analysis summaries above, Option 3 “An 8CPA which focusses on dispensing remuneration and CPPs delivered directly through community pharmacies” was the preferred option. This option is expected to provide the greatest certainty while also giving the flexibility and opportunity to consider wholesaler arrangements and program reforms in collaboration with a wider group of interested stakeholders.

Option 1 would result in considerable uncertainty to the community pharmacy sector and the wider community as future remuneration for dispensing PBS medicines would be subject to an independent inquiry by the PBRT. The impacts on Government funding and reform of CPPs would also be less certain than other options.

Option 2 would result in large increases to patient and community costs and limit the opportunity to undertake comprehensive consultation in relation to wholesaler arrangements and CPPs. Existing arrangements for CPPs would largely be extended should Option 2 be implemented.

Option 3 will provide for the greatest alignment of the outcomes to be delivered by the 8CPA with the objectives of the NMP. Option 3 separates aspects of dispensing revenue and CPPs delivered in community pharmacies from special arrangements for wholesalers of PBS medicines professional education and certification activities within the 8CPA. This will allow the Government to appropriately prioritise and consider, in collaboration with all relevant stakeholders, proposed reforms to these areas on an ongoing basis.

If Option 3 is implemented, outside of the 8CPA the Department will seek to work with key stakeholders including PSA, community organisations, and consumer organisations to review and establish evaluation frameworks for programs relating to home medicines reviews, workforce and First Nations. This will address a key theme raised throughout the consultation process, that being a desire for greater collaboration and multiple agreements, whilst still meeting the requirement of the Act.

Implementation

Implementation of Option 3 will require negotiation and signing of a suitable agreement with the Guild. Following the formal signing of an 8CPA, the Department will, as soon as practicable, draft the necessary legislative instrument or amendments to the *Commonwealth price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020*. A meeting of the PBRT will be arranged to give effect to relevant changes to the Commonwealth price consistent with the agreement through the drafted legislative instrument.

Minor amendments will also be required to the following legislative instruments which refer to the 7CPA:

- *National Health (Commonwealth Price—Pharmaceutical benefits supplied by private hospitals) Determination 2020*
- *National Health (Commonwealth Price—Pharmaceutical Benefits Supplied By Public Hospitals) Determination 2017*
- *National Health (Pharmaceutical Benefits) (subsection 84C(7) Price) Determination 2019*
- *National Health (Remote Area Aboriginal Health Services Program) Special Arrangement 2017*
- *Repatriation Pharmaceutical Benefits Scheme*

The Department will continue negotiations with relevant pharmacy stakeholders, including the Guild, in relation to:

- Arrangements for wholesalers of PBS medicines (primary stakeholder NPSA), including wholesaler mark-up and CSO arrangements
- Review and establishment of evaluation frameworks for the CPPs included in the CPA (primary stakeholders the Guild, PSA and consumer organisations), and
- Review of Pharmacy Programs and Clinical Services (existing and new) to be delivered outside of the CPA (primary stakeholders PSA and consumer organisations).

Until these further negotiations are finalised and a future decision of Government occurs it is intended that the existing wholesaler arrangements and CPPs will continue largely unchanged. To ensure this is possible the Department will develop a suitable service agreement with a third-party administrator for the delivery of both the CPPs outlined in the 8CPA and other existing CPPs from the 8CPA's execution date.

The Department in collaboration with the relevant administrator will create and distribute any relevant updated program documentation including Programs rules, consent forms and General Terms and Conditions for participation under the programs.

As soon as an announcement has been made the Department in collaboration with the administrator and key pharmacy stakeholders including the Guild, will ensure appropriate communication to notify the community, health professionals, pharmacists and consumers of the commencement of the 8CPA and CPPs arrangements.

The Department will continue consultations with a broad base of stakeholders, as outlined above, to discuss the ongoing, future delivery of those programs which are outside of a CPA. A review of the CPPs outlined in the 8CPA, including an assessment of their health benefits and cost effectiveness in consultation with relevant stakeholders is expected to be completed by early 2026. Following this review it is expected that a proposal for program redesign and development of suitable evaluation frameworks will be completed by mid-2026.

The inclusion of CPPs within the CPA creates some risk of there being a reluctance from stakeholders to deliver continuous improvement and innovation through those CPPs. To mitigate this risk under Option 3 the 8CPA would include a commitment from both Government and the Guild to establish quality and evaluation frameworks for the CPPs, within the first 3 years of the CPA.

The movement of some smaller pharmacy programs, which primarily focus on workforce and pharmacists delivering services in the home or care settings, outside the auspices of the CPA will further ensure an ongoing reform effort with appropriate broad-based stakeholder consultation.

The establishment of evaluation frameworks for those individual CPPs outside of the CPA will be reported publicly and will be open to comment and input from interested stakeholders including consumer groups and members of the public. Evaluations of the CPPs undertaken by, or on behalf of, the Department will be published in a timely manner to enable interested parties to provide input into any proposed changes to the program examined. Any changes to existing programs or any new programs will have the details of the program including details of eligibility published by the Department.

Communications

The Department will prepare communication materials, for consumers and businesses, to outline the ways in which the 8CPA aims to improve on the 7CPA. This includes:

- Continuing to deliver cheaper medicines for consumers
- Increasing stakeholder engagement and innovation by separating the negotiations for wholesaler arrangements and CPPs not directly delivered by community pharmacy from the CPA, and
- Simplifying indexation arrangements for dispensing costs.

Updates will be made to the websites outlining PBS medicine costs to reflect the changes to pricing as implemented and revised as indexation occurs in line with the agreement.

Further communications with key stakeholders will be developed to outline the ongoing opportunities to contribute to the review and evaluation of CPPs and encourage broad participation in this future work program.

7. How will you evaluate the chosen option against the success metrics?

The Department will develop a comprehensive evaluation framework that will monitor risks and provide mitigation strategies should unforeseen circumstances arise.

Evaluation questions

To aid in the evaluation of the 8CPA the Department will consider the following key questions:

- How has the policy made things better for people in Australia?
- Was the policy effective in supporting the objectives of the NMP?
- Was the policy efficient (i.e. did it achieve its outcomes at least cost)?

The mechanisms through which such evaluation will be achieved are further outlined below in alignment with the objectives of Government underpinning this proposal as outlined in section 2.

Evaluation framework for CPPs

It is proposed that the 8CPA includes a commitment to the development, in collaboration with the key stakeholders, of evaluation frameworks for all CPPs outlined in the 8CPA. This process will formally begin with the signing of the 8CPA.

The Department expects this process to conclude by mid-2026, noting the need for timely delivery of quality evaluation frameworks to inform future Government decision-making on funding and reform options for these programs as may be part of a further CPA negotiation. This would bring the relevant programs into line with best government practice where regular reviews of government funded programs ensure these demonstrate the effective and efficient use of government resources under the PGPA Act.⁷⁵ The Government is not restricted by negotiated commitments in its ability to evaluate and improve the operation of publicly funded programs, with the interests of the Australian community at the centre.

The evaluation framework development process will begin with the development of a data collection methodology, which will rely on both existing and new forms of data collection as agreed with industry stakeholders. Data for relevant pharmacy programs are monitored and published monthly on the Department's website. The data currently available largely relate to volumes and expenditure and while this provides some insight to the need for such programs, further improvements could be made by developing and implementing approaches to monitor and evaluate the health outcomes achieved through each of the programs. By making consideration of these improvements a part of an 8CPA, the Department and the Guild can facilitate participation from the necessary stakeholders to inform the development of additional data collection processes that are both efficient and not overly onerous for the pharmacist.

⁷⁵ <https://www.finance.gov.au/government/setting-commonwealth-entity/governance-compliance>

The additional data will allow for a more robust clinical and cost-effectiveness study methodology across the CPPs. This will inform both the 'baseline' review and the processes required for the ongoing administration of the relevant pharmacy program evaluation frameworks as part of business-as-usual processes.

This work will culminate in the identification of necessary program changes, and any potential reform options, as part of the program evaluation processes. Due to the ongoing involvement and investment of all key stakeholders in these reform efforts, the Department will aim towards implementing these changes, along with business-as-usual processes stemming from the evaluation frameworks for each program, ahead of the conclusion of the 8CPA. Through this work, the Department will be better informed and positioned to discuss the funding and administration of programs under a potential 9CPA.

1. Person-centred

As discussed above the provision of dispensing remuneration supports access to timely and easy-to-understand information on the safe use of PBS medicines by ensuring that pharmacists, as a part of their core role when dispensing medicines, are able to undertake the relevant checks, and consult with patients when required. In addition, the 7CPA and previous CPAs have included a number of person-centred CPPs which enable the provision of additional specific pharmacy support services for patients. The volume of services provided is reported monthly and shows that these services have generally continued to have moderate growth over the life of the 7CPA. CPP data are available on the Department website at <https://www.health.gov.au/resources/collections/pharmacy-programs-data>.

To further build a person-centred approach the 8CPA will encourage greater inclusion of consumer representative stakeholders in consultations for the review and establishment of specific evaluation frameworks for each of the CPPs relating to medication management included and in the 8CPA as well as in future CPP development. This broad consultation will help to ensure that consumer views are incorporated into the design of CPPs and that the interests of patients are placed at the heart of the programs.

The evaluation frameworks developed in consultation with stakeholders will be used to determine what data need to be collected to allow a thorough evaluation of the clinical benefit and cost effectiveness. If no or limited clinical benefit was determined after evaluation the money for that program may be directed to other better performing programs or to other services that could provide the clinical benefit that the initial program was designed to deliver.

This objective will be evaluated by the inclusion of consumer focussed stakeholders in the review of CPPs and establishment of suitable evaluation frameworks for the individual 8CPA programs which take into consideration consumer views. A successful evaluation against an established framework will lead to publishable outcomes and possible changes to the evaluated program. The volume of services provided through CPPs will also continue to be monitored and analysed.

2. Equity, sustainability and Access for Consumers and Businesses

As the objectives of equity, sustainability and access for consumers and businesses are closely linked, the evaluation of these objectives will be discussed together. In meeting this objective the 7CPA outlined growth of dispensing remuneration over 5 years. Dispensing remuneration is closely monitored and its trajectory compared to both that forecasted and the overall growth in the PBS. Over the first three years of the 7CPA, actual remuneration provided to pharmacies was greater than originally agreed as a result of higher prescription volumes and more medicines being listed and supplied through the PBS as well as high consumer price indexation rates. This additional volume/remuneration was somewhat counteracted through the introduction of 60-day dispensing which is expected to reduce the number of scripts dispensed.

The 7CPA also included agreement on CSO and wholesaler arrangements, a Regional Pharmacy Maintenance allowance and a number of smaller CPPs aimed at assisting in the maintenance of rural and indigenous workforce. The volume of these CPPs accessed is reported on quarterly and generally shows slow but steady growth.

The outcomes of the above measures collectively can be further informed by monitoring the ongoing number and distribution of community pharmacies. As would be anticipated over the life of the 7CPA there has been very slow growth in the number of approved pharmacies.

To enable further focus on these core objectives of equity, sustainability and access the 8CPA will not include wholesaler arrangements or the workforce, rural and indigenous focussed CPPs. These arrangements will instead be negotiated separately with the most relevant stakeholders. This will provide for broader reform in these areas and allow for these arrangements to be better targeted to meet the needs for consumers, including First Nations Peoples, and businesses in regional and remote areas.

Success against these objectives will continue to be monitored and evaluated through analysis of PBS dispensing data. To evaluate affordable access for the community, the total growth in PBS Government expense for the supply of medicines for future financial years will be monitored. The total cost to patients for medicines priced below the level of the patient co-payment (i.e. patient contributions through under co-payment prescriptions) and dispensing remuneration data will also continue to be monitored.

In addition, success of this objective for the 8CPA will be informed by the establishment of separate arrangements in relation to:

- wholesaler arrangements, negotiated and signed by wholesaler stakeholders.
- CPPs relating to pharmacy workforce and rural and remote pharmacies as well as First Nations specific programs developed with a broad range of stakeholders.

The CPPs will be reviewed in collaboration with relevant stakeholders, outside of the CPA. Reforms to the existing CPPs or new proposals will include the establishment of appropriate evaluation frameworks which provide for the analysis of the outcomes achieved and the cost effectiveness of each program.

3. Accountability and Transparency

As discussed earlier the 7CPA included the strongest and most specific clauses to date in relation to increasing the transparency of pharmacy charges. As a direct result of this undertaking the Guild has developed a range of in pharmacy resources aimed at assisting pharmacists in improving general understanding of PBS medicine costs including dispensing charges. These resources in practice however have done little to improve the transparency of the actual cost of dispensing remuneration and pharmacy charges for consumers.

To encourage further transparency the 8CPA will recognise that the Government will undertake further work to confirm that pharmacists are responsible for ensuring that consumers are made aware of the components of the costs of their medicines prior to them being dispensed.

To assist in this evaluation and analysis the additional support of consumer focussed stakeholder groups may be sought to both the co-designing and undertaking of representative surveys as a source of evidence for changes in consumer awareness and understanding of relevant charges.

4. Supporting stronger collaboration and innovation

As discussed in earlier sections, successive CPAs have sought to encourage collaboration and innovation across the pharmacy sector. A number of pharmacy program pilots and trials were established under the 6CPA. During the 7CPA the results and outcomes from these trials and other reviews were used to inform MSAC consideration of the CPPs. The outcomes and feedback from the MSAC consideration will be used to inform the review of CPPs included in the 8CPA as well as the establishment of appropriate evaluation frameworks.

The evaluation of CPPs will require designing individual evaluation frameworks as outlined in the implementation section above. This evaluation framework will be used to determine what data need to be collected to allow a thorough evaluation of the clinical benefit and cost effectiveness. If no or limited clinical benefit was determined after evaluation the money for that program may be directed to other better performing programs or to other services that could provide the clinical benefit that the initial program was designed to deliver.

Success against this objective will be evaluated through stakeholder engagement in the design and establishment of appropriate evaluation frameworks to enable the ongoing analysis of the health outcomes achieved and the cost effectiveness of each program.

Monitoring stakeholder impacts

In addition to the development of a comprehensive evaluation framework to measure success and mitigate unforeseen issues, the Department is also committed to evaluating the impacts of implementation of the proposal on all affected stakeholders through existing mechanisms. Suggested changes to improve clinical outcomes will be incorporated into programs and services as soon as possible. Evaluation will be ongoing for the life of any agreement and will relate to individual components as outlined below. The Department is committed to ongoing consultations with key stakeholders in the community pharmacy space, including the Guild, PSA, NPSA and consumer organisations to ensure that the goals of the agreement as outline in Section 2 above are being met.

Community pharmacy sector

The Department will continue to monitor the impact on the community pharmacy sector. Remuneration for dispensing PBS medicines will continue to be monitored by the Department through existing mechanisms, as outlined above. Actual expenditure data are supplied by Services Australia and tracked on an annual basis by the Department. Participation of community pharmacies in pharmacy programs will be monitored by the Department and reported on the Health website as is currently undertaken, to ensure that access to these programs is maximised for all Australians. Any changes in these metrics that indicate a lessening of access to medicines and services for consumers will trigger the Department to look at measures to restore equitable access.

The Department will also monitor the number and distribution of pharmacies across Australia to ensure businesses continue to be viable and provide convenient means of access to medicines for all Australians. Currently the Department receives monthly statistics on the number of pharmacy applications to move, change owners, open a new premises or close an existing pharmacy. The Department then tracks this data with reference to population data to ensure that access to pharmacies remains at similar levels or improves. The distribution of pharmacies is also tracked by the Department ensuring that rural and remote communities are not adversely affected by any proposed closures.

Wholesalers

The Department will monitor the ongoing remuneration to wholesalers through existing mechanisms, with the financial data provided by the administrator of the CSO and Services Australia. The viability and performance of wholesalers to supply medicines to all pharmacies will be monitored to ensure that no adverse effect on supply to pharmacies outside of metro areas has resulted as a consequence of the implementation. Regular meetings with the NPSA will continue for the life of any agreement to further ensure that access to medicines supplied through the wholesalers is not adversely affected by Government action.

Consumers

Impacts on consumers' access to medicines will be monitored through the Department monitoring the viability and distribution of community pharmacies as above, and the ongoing collection and monitoring of PBS medicines prescribed and dispensed to patients. The Department will continue publishing data

on PBS medicines trends, including through the annual PBS Expenditure and Prescriptions reports. Use of pharmacy programs will continue to be monitored through the volume of services provided, with this data published, as currently available, on the Health website. Consumer organisations will be involved in consultations regarding development of pharmacy program evaluation frameworks and any proposed changes to programs that may eventuate from their evaluation.

APPENDICES

1. Abbreviations

ACCHO	Aboriginal Community Controlled Health Organisation
ACPA	Australian Community Pharmacy Authority
the Act	<i>National Health Act 1953</i>
ADHA	Australian Digital Health Agency
AEMP	Approved Ex-Manufacturer Price
ANAO Audit	Australian National Audit Office's audit of the Administration of the Fifth Community Pharmacy Agreement
AOC	Agreement Oversight Committee
Compact	2017 Strengthening PBS Compact
CPA	Community Pharmacy Agreement
6CPA	Sixth Community Pharmacy Agreement
7CPA	Seventh Community Pharmacy Agreement
8CPA	Eighth Community Pharmacy Agreement
CHF	Consumers Health Forum of Australia
CMI	Consumer Medicines Information
CPCC	Community Pharmacy Consultation Committee
CPSF	Community Pharmacy Stakeholder Forum
CPP	Community Pharmacy Program
CSO	Community Service Obligation
CTG	Closing the Gap
DAA	Dose Administration Aid
Department	Department of Health and Aged Care
EPF	Electronic Prescription Fee
GBMA	Generic and Biosimilars Association
Guild	The Pharmacy Guild of Australia
HMR	Home Medicines Review

IA	Impact Analysis
IDAA	Indigenous Dose Administration Aids program
IPP	Indigenous Pharmacy Programs
KPM	Key Performance Measures
Location Rules	Pharmacy Location Rules
MDQ	Maximum Dispensed Quantity
MSAC	Medical Services Advisory Committee
NACCHO	National Aboriginal Community Controlled Health Organisation
NDSS	National Diabetes Services Scheme
NIP	National Immunisation Program
NMP	National Medicines Policy
NPSA	National Pharmaceutical Services Association
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
PSCC	Pharmacy Stakeholder Consultation Committee
PES	Prescription Exchange Service
Pharmacy Review	Review of Pharmacy Remuneration and Regulation
PPA	Pharmacy Programs Administrator
PBRT	Pharmaceutical Benefits Remuneration Tribunal
PIR	Post-Implementation Review
PSA	Pharmaceutical Society of Australia
QUM	Quality Use of Medicines
RAM	Remuneration Adjustment Mechanism
RMMR	Residential Medication Management Review
RPBS	Repatriation Pharmaceutical Benefits Scheme
RPMA	Rural / Regional Pharmacy Maintenance Allowance
TGA	Therapeutic Goods Administration

2. Glossary

Approved Ex-Manufacturer Price (AEMP)	The price charged by a manufacturer for medicines listed on the Pharmaceutical Benefit Scheme (PBS), as agreed between the Australian Government and the manufacturer
Approved pharmacist	A pharmacist approved under section 90 of the <i>National Health Act 1953</i> to supply pharmaceutical benefits (i.e., to dispense Pharmaceutical Benefits Scheme subsidised medicines) from a particular premises
Brand Price Premium	An additional price paid by a patient for a more expensive brand of a Pharmaceutical Benefits Scheme (PBS) medicine, arising where a medicine manufacturer has set the price of that medicine higher than the cheapest brand, in the case where a number of therapeutically equivalent brands are available on the PBS
Community pharmacy	A retail pharmacy premises from which patients may obtain a range of medicines and other health related products, including prescription and over the counter medicines. In addition to dispensing medicines, pharmacists in community pharmacies may also provide advice on the appropriate use of medicines, as well as medication management and other services, including vaccinations and wound management
Community Service Obligation (CSO)	The primary objective of the CSO Funding Pool is to ensure that arrangements are in place to provide all Australians with ongoing and timely access to all PBS Medicines, through Community Pharmacies. Under the CSO Funding Pool arrangements, eligible entities, known as CSO Distributors, receive Payments from the CSO Funding Pool for supplying PBS Medicines to Community Pharmacies
Controlled Drug	A medicine containing a substance included in Schedule 8 of the Poisons Standard (Cwlth)
Dose administration aid	A sealed medicine packaging system designed to reduce unintentional medication non-adherence by organising doses of a patient's medicines according to time of administration and enabling patients to see if they have taken their medicines
Home Medicines Review (HMR)	A medication review conducted by an accredited pharmacist in a patient's home. An HMR is initiated at the request of an eligible patient's referring medical practitioner and involves an initial face-to-face patient consultation with a pharmacist with one more follow-up consultations as required, each time after which a written assessment is provided to the patient's referring medical practitioner
Medication Review	A systematic assessment of a patient's medication management with the aim of optimising the quality use of medicines and minimising medication-related problems
National Diabetes Services Scheme (NDSS)	An Australian Government program, administered by Diabetes Australia, to enhance the capacity of people with diabetes to understand and self-manage their condition and to provide patients access to services, support and subsidised diabetes products
Over-the-counter medicines	Medicines that are used to treat mild health conditions and which do not require a prescription for supply. These can be:

	<ul style="list-style-type: none"> • <i>Pharmacist Only Medicines</i> – which can only be supplied from a pharmacy on the advice of a pharmacist; • <i>Pharmacy Medicines</i> – which are available for self-selection from pharmacies only; or • <i>Non-Scheduled Medicines</i> – which are available for self-selection from pharmacies, supermarkets or health foods stores.
Prescription medicines	Medicines that can only be made available to a patient on the written instruction of a health practitioner authorised under state or territory legislation to prescribe. This usually pertains to medicines containing a substance included in Schedule 4 or Schedule 8 of the Poisons Standard (Cwlth)
Pharmacy Location Rules	Rules relating to the establishment of a new pharmacy, or the relocation of an existing pharmacy, approved to supply pharmaceutical benefits under section 90 of the <i>National Health Act 1593</i> (Cwlth). The rules set out location-based criteria which must be met for the Australian Community Pharmacy Authority (ACPA) to recommend approval under section 90 of the Act. The Rules are legislated under the <i>National Health (Australian Community Pharmacy Authority Rules) Determination 2018 (PB 46 of 2018)</i> , made under section 99L of the Act
Community Services Obligation (CSO)	The CSO encompasses a set of service standards and compliance requirements, pertaining to the stocking and distribution of PBS medicines to community pharmacies across Australia, which medicines wholesalers must comply with when becoming a CSO Distributor eligible for receiving payments under CSO Funding Pool arrangements administered under the 7CPA
CSO Funding Pool	A pool of funds, totalling \$1.083 billion over five years under the 7CPA, to support eligible CSO Distributors for the additional costs incurred in ensuring the timely supply of Pharmaceutical Benefit Scheme (PBS) medicines and National Diabetes Services Scheme (NDSS) products to community pharmacies across Australia
QUM in Aged Care	The Quality Use of Medicines (QUM) Program supports the delivery of services and activities by pharmacists aimed at supporting the quality use of medicines, including the safe use of medicines, within Australian Government-funded aged care facilities
Residential Medication Management Review (RMMR)	A medication review conducted in an Australian Government funded Aged Care Facility by an accredited pharmacist for a patient living in that facility. An RMMR is initiated at the request of an eligible patient’s referring medical practitioner and involves an initial face-to-face patient consultation with a pharmacist with one more follow-up consultations as required, each time after which a written assessment is provided to the patient’s referring medical practitioner
S100 – Highly Specialised Drugs Program	The Highly Specialised Drugs (HSD) Program provides access to specialised Pharmaceutical Benefits Scheme (PBS) medicines for the treatment of chronic conditions which, because of their clinical use and other special features, have restrictions on where they can be prescribed and supplied. In most cases, medical practitioners are required to undertake specific training or be affiliated with a specialised hospital unit to prescribe these

	medicines. HSDs may be prescribed through public or private hospitals, or in limited instances, in the community setting
S100 Pharmacy Support Allowance	An allowance paid to approved pharmacists that provide support to remote area Aboriginal Health Services in relation to Section 100 Supply Arrangements
S100 Supply Arrangements	Supply of Pharmaceutical Benefit Scheme (PBS) medicines to remote area Aboriginal Health Services under the provisions of section 100 of the <i>National Health Act 1953</i>
Special Pricing Arrangement	A deed of agreement between a medicine sponsor and the Australian Government, for supply of a medicine at a price recommended by Pharmaceutical Benefits Advisory Committee (PBAC) as cost-effective, without affecting the price of the medicine in other markets. Special Pricing Arrangements formalise a 'published' versus 'effective' pricing component, where the difference between the published price in the Schedule of Pharmaceutical Benefits and the price actually paid by the Commonwealth (the 'effective' price), is managed through a rebate arrangement
Staged Supply	An in-pharmacy service involving the supply of Pharmaceutical Benefit Scheme (PBS) medicines to a patient in instalments when requested by the prescriber. The program is designed to assist patients who are at risk of drug dependency or who are otherwise unable to manage their medicines safely

3. Jurisdictional ownership rules

Jurisdiction	Who can own/have a financial interest	How many can be owned/have a financial interest by one individual/entity
Australia Capital Territory	<ol style="list-style-type: none"> 1. a pharmacist, 2. a complying pharmacy corporation, or 3. a former corporate pharmacist <p>Note: Friendly societies are excluded from ownership</p>	No maximum limit legislated
Queensland	<ol style="list-style-type: none"> 1. a pharmacist; or 2. a corporation whose directors and shareholders are all pharmacists; or 3. a corporation: <ol style="list-style-type: none"> i. whose directors and shareholders are a combination of pharmacists and relatives of the pharmacists (defined as the pharmacist's spouse or a child of the pharmacist who is at least 18 years of age); and ii. in which the majority of shares are held by pharmacists; and iii. in which only pharmacists hold voting shares; or iv. a friendly society; or v. Mater Misericordiae Health Services Brisbane Limited. 	<p>A pharmacist or eligible corporation no more than five (5).</p> <p>Friendly societies and Mater Misericordiae Health Services Brisbane Limited no more than six (6)</p>
New South Wales	<ol style="list-style-type: none"> 1. a registered pharmacist, 2. a partnership of registered pharmacists, 3. a pharmacist's body corporate (as defined in the National Law (NSW)), and 4. a friendly society with a prior written approval from the Minister of Health (NSW). 	Each entity can hold a financial interest in up to five (5) pharmacies.
Northern Territory	<ol style="list-style-type: none"> 1. A pharmacist; 2. a partnership of which all partners are pharmacists; 3. a corporation of which all shareholders and directors are pharmacists; 4. an Aboriginal health service or friendly society that has been granted an exemption by the Minister 	No maximum limit legislated Ministerial approval required for Friendly Society applications.
South Australia	<ol style="list-style-type: none"> 1. A pharmacist; or 2. a corporation whose directors and shareholders are all pharmacists; or 3. a corporation: <ol style="list-style-type: none"> i. whose directors and shareholders are a combination of pharmacists and relatives of the pharmacists, ii) a friendly society iii) Friendly Society Medical Association Limited; or iv) The Mount Gambier United Friendly Societies Dispensary Limited. 	Limited to six (6) for Pharmacists and forty (40) for Friendly Society Medical Association Limited and 9 for other friendly Societies.
Tasmania	<ol style="list-style-type: none"> 1. An individual pharmacist 	Limited to four (4) for Pharmacists and friendly Societies

	<p>2. a partnership where all partners are registered pharmacists</p> <p>3. a company with each director who is a registered pharmacist and the controlling interest (i.e. more than 50% of the voting shares) is held by one or more registered pharmacists</p> <p>4. an individual or a body corporate as trustee for a discretionary (family) trust. The beneficiaries are limited to the registered pharmacist and/or their close relatives,</p> <p>5. an individual or a body corporate as trustee for a unit trust, provided that all unit holders must be registered pharmacists or close relatives</p>	
Victoria	<p>1. a partnership of registered pharmacists, or</p> <p>2. a partnership of registered pharmacist(s) and one or more eligible companies, or a partnership of eligible companies</p>	A registered pharmacist, or pharmacy company, cannot own nor have a financial interest in more than five (5) separate pharmacy businesses
Western Australia	<p>1. a pharmacist; or</p> <p>2. a person who is a partner in a partnership that carries on the business and in which every partner is either —</p> <p>(i) a pharmacist; or</p> <p>(ii) a close family member of a partner who is a pharmacist; or</p> <p>3. a pharmacist controlled company; or</p> <p>4. a friendly society; or</p> <p>5. the preserved company.</p>	A pharmacist or close family member must not own, or hold a proprietary interest in, more than four (4) pharmacy businesses.

4. Comparative Commonwealth price under previous CPAs

The tables below set out details of the contributions that were expected to be made during the terms of the fifth, sixth and seventh community pharmacy agreements. This information has been consolidated from each of the individual agreements and does not present the actual costs, which are dependent on script volumes over their life of each agreement or any indexation applied throughout the life of the agreement.

Table 1: Components of the remuneration and funding

Component	Contributor	5CPA 2010 \$million (estimated)	6CPA 2015 \$million (estimated)	7CPA 2020 \$million (estimated)
Pharmacy remuneration for the dispensing of Pharmaceutical Benefits that are Commonwealth subsidised, including dispensing fee, Administration Handling and Infrastructure Fee and Dangerous Drug fee	Commonwealth	\$13,771.60 [#]	\$11,112	\$11,757
	Patient		\$3,025	\$2,177
Remuneration for wholesalers to hold and deliver subsidised Pharmaceutical Benefits to Approved Pharmacists (excluding the Community Service Obligation)	Commonwealth		\$1,414	\$1,746
	Patient		\$385	\$320
Pharmacy remuneration for the dispensing of Pharmaceutical Benefits that are not Commonwealth subsidised*, including wholesaler remuneration, dispensing fee, Administration Handling and Infrastructure Fee and Dangerous Drug fee	Commonwealth			N/A
	Patient			\$6,954
Community Pharmacy Programs	Commonwealth	\$663.4	\$1,263	\$1,400
	Patient		As set under the Community Pharmacy Programs	As set under the Community Pharmacy Programs
Community Service Obligation funding	Commonwealth	\$949.50	\$976	\$1,083
	Patient	N/A	N/A	N/A
Fees for Community Service Obligation distributors to distribute National Diabetes Services Scheme products	Commonwealth		\$28	\$33
	Patient		NA	N/A
Fees for pharmacy to distribute National Diabetes Services Scheme products	Commonwealth		\$28	\$33
	Patient		No additional patient charge	No additional patient charge
Total**	Commonwealth	15,384.5	\$15,476	\$15,852
	Patient [^]	Not available	\$3,410	\$9,451
	Total	Not available	\$18,886	\$25,303

[#] Includes dispensing fee, pharmacy and wholesale mark-up, extemporaneously prepared and dangerous drug fees, premium free dispensing incentive and electronic prescription fee

^{*}**Note:** the price that patients pay for prescriptions that are not Commonwealth subsidised may be subject to discretionary discounting and the application of additional allowable fees by Approved Pharmacists. Accordingly, total remuneration for dispensing PBS medicines where the Commonwealth does not subsidise the cost to the patient of the medicine is in no way assured by the Commonwealth.

^ Greater transparency of total dispensing remuneration costs has been provided in successive CPA's thus the total costs have not truly increased overtime.

**The total excludes remuneration when community pharmacies dispense medicines under section 100 special arrangements. Chemotherapy compounding fees will be paid directly to chemotherapy compounders, who may not be Approved Suppliers.

Table 2: Components of the Commonwealth price⁷⁶

Payment type	Value of payment 2010		Value of payment 2015		Value of payment 2017		Value of payment (2020)	
wholesale mark-up ^{[77][78]} (for Ready-Prepared Pharmaceutical Benefits)							Where the Ex-Manufacturer Price is up to and including \$5.50	\$0.41 per dispense
	Up to and including \$930.06	7.52% mark-up on ex-manufacturer's price	Where the Ex-Manufacturer Price is up to and including \$930.06	7.52 per cent of the Ex-Manufacturer Price per dispense	Where the Ex-Manufacturer Price is up to and including \$930.06	7.52 per cent of the Ex-Manufacturer Price per dispense	Where the Ex-Manufacturer Price is over \$5.50 and up to and including \$720	7.52 per cent of the Ex-Manufacturer Price per dispense
	Over \$930.06	\$69.94	Where the Ex-Manufacturer Price is over and including \$930.06	\$69.94 per dispense	Where the Ex-Manufacturer Price is over and including \$930.06	\$69.94 per dispense	Where the Ex-Manufacturer Price is over \$720	\$54.14 per dispense
Administration, Handling and Infrastructure Fee ^[79]	(mark-up on Approved Price to Pharmacist) Up to and including \$30.00	15.0%	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 less than \$180	\$3.62 plus the Additional AHI Fee for the relevant Financial Year, per dispense	For a Listed Brand with a Price to Pharmacists for Maximum Quantity less than \$100	\$4.28 per dispense of Maximum Quantity

⁷⁶ Fees for the first level of AHI, dispensing fee and dangerous drug fee are subject to annual indexation as outlined in each CPA.

^[77] The wholesale mark-up for a Pack Quantity of a Listed Brand is calculated using the Relevant Quantity.

^[78] The wholesale mark-up applying for the period from 1 July 2020 to 31 December 2020 will be the wholesale mark-up applying in the last year of the Sixth Community Pharmacy Agreement. The wholesale mark-up arrangements set out in Table 2 will commence from 1 January 2021.

^[79] The AHI Fee is calculated from the per pack price with the AHI Fee applied for the Maximum Quantity proportionate to the number of packs required for the Maximum Quantity, and will be adjusted if less or more than the Maximum Quantity is supplied. Refer to the Determination for further details of the AHI Fee calculation.

^^ Multiple additional tiers were included in 5CPA which has not been reflected here

Payment type	Value of payment 2010		Value of payment 2015		Value of payment 2017		Value of payment (2020)	
	Between \$180.01 and \$450.00	\$18.00	For a pack quantity of a Listed Brand with a Price to Pharmacists from \$180 and to \$2,0989.71	\$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 from \$180 and to \$2,0989.71	\$3.62 plus the Additional AHI Fee for the relevant Financial Year and 3.5% of the amount by which the Price to Pharmacists for Maximum Quantity exceeds \$180, per dispense	For a Listed Brand with a Price to Pharmacists for Maximum Quantity from \$100 and up to and including \$2,000	Tier One AHI Fee plus 5% of the amount by which the Price to Pharmacists for Maximum Quantity exceeds \$100, per dispense of Maximum Quantity
	Over \$1750.00^^	\$70.00	For a pack quantity of a Listed Brand with a Price to Pharmacists more than \$2,0989.71	\$70.00 per dispense	For a pack quantity of a Listed Brand with a Price to Pharmacists more than \$2,0989.71	\$72.43 per dispense	For a Listed Brand with a Price to Pharmacists for Maximum Quantity over \$2,000	Tier One AHI Fee and \$95 per dispense of Maximum Quantity
dispensing fee (for Ready-Prepared Pharmaceutical Benefits)	\$6.42		\$6.93 per dispense		\$7.15 per dispense		\$7.74 per dispense	
dispensing fee (for Extemporaneously-Prepared Pharmaceutical Benefits)	\$2.04		Dispensing fee for Ready-Prepared Pharmaceutical Benefits, plus \$2.04, per dispense		Dispensing fee for Ready-Prepared Pharmaceutical Benefits, plus \$2.04, per dispense		Dispensing fee for Ready-Prepared Pharmaceutical Benefits, plus \$2.04, per dispense	
Dangerous Drug fee	\$ 2.71		\$2.91 per Dangerous Drug dispensed		\$3.01 per Dangerous Drug dispensed		\$4.80 per Dangerous Drug dispensed	
Total (assuming maximum wholesale mark-up and AHI)	\$151.11		\$151.82		\$154.57		\$168.00	

5. Community Pharmacy Programs in the 7CPA

PROGRAM	BACKGROUND
MedsCheck and Diabetes MedsCheck	<p>The MedsCheck and Diabetes MedsCheck programs provide for an in-pharmacy medication management review between a patient and registered pharmacist to enhance quality use of medicines and reduce adverse drug events.</p> <p>Pharmacies who offer the service may conduct up to 20 MedsChecks/Diabetes MedsChecks per calendar month.</p>
Home Medicines Review (HMR)	<p>The HMR commenced in 2001 and funds comprehensive medication reviews for people living in the community to reduce the risk of medication misadventure and optimise the benefits achieved from medication treatment.</p>
Staged Supply (SS)	<p>SS provides for the provision of medication in instalments where requested by a prescriber, with the aim to improve medication adherence.</p> <p>Each community pharmacy taking part in the program is funded to support up to 15 patients per month.</p>
Dose Administration Aids (DAA)	<p>DAAs are provided with the aim of assisting people with the management and timing of their medicines. A DAA is a well-sealed, tamper-evident device that allows individual medicine doses to be organised according to the prescribed dose schedule.</p>
Indigenous Dose Administration Aids (IDAA)	<p>The IDAA Program closely mirrors and runs parallel with the broader DAA Program with a few key differences, including:</p> <ul style="list-style-type: none"> • Patient eligibility criteria to support Aboriginal and/or Torres Strait Islander patients; • Access to the Program will be uncapped, unlike the broader DAA Program, which has weekly service caps applied to individual pharmacies.
Residential Medication Management Review (RMMR) and Quality Use of Medicines (QUM)	<p>Established in 1997 under the Second Community Pharmacy Agreement (2CPA), the RMMR program provides for a review of a patient's medication information in a Government funded Residential Aged Care Facility (RACF).</p> <p>From 1 October 2011, the QUM service components were separated out as an individual fee. QUM service focuses on improving practices and procedures as they relate to the quality use of medicines in a residential care facility.</p>

PROGRAM	BACKGROUND
Rural Pharmacy Workforce Programs	<p>These programs aim to maintain and improve access to quality community pharmacy services in rural communities and strengthen and support the rural pharmacy workforce and include:</p> <ul style="list-style-type: none"> • Administrative Support to Pharmacy Schools Scheme (Admin) • Emergency Locum Service (ELS) • Home Medicines Review Rural Loading Allowance (HMR-RLA) • Intern Incentive Allowance for Rural Pharmacies (IIARP) • Intern Incentive Allowance for Rural Pharmacies Extension program (IIARP-EP) • Rural Continuing Professional Education Allowance (CPE) • Rural Intern Training Allowance(RITA) • Rural Pharmacy Liaison Officer Program (RPLO) • Rural Pharmacy Scholarship Mentor Scheme (RPSS-Mentor)Rural Pharmacy Scholarship Scheme (RPSS) • Rural Pharmacy Student Placement Allowance Program (RPSPA) <p>The programs are intended to recruit, train, support and retain pharmacists for regional, rural, and remote areas, including intern incentives, undergraduate and postgraduate scholarships, continuing professional education allowance and an emergency locum scheme.</p>
Regional Pharmacy Maintenance Allowance (RPMA)	<p>The RPMA provides financial assistance to eligible regional, rural and remote pharmacies.</p>
Aboriginal and Torres Strait Islander Pharmacy Assistant Traineeship Scheme (ATSIPATS)	<p>This scheme supports Aboriginal and Torres Strait Islander participation in the pharmacy workforce, which in turn is intended to provide culturally appropriate pharmacy services to better meet the needs of First Nations communities and patients.</p> <p>A maximum allowance of \$10,000 is available to a community pharmacy that employees and supports a trainee through the course of their studies (up to two years).</p>
Aboriginal and Torres Strait Islander Pharmacy Scholarship Scheme (ATSIPSS)	<p>The aim of the Aboriginal and Torres Strait Islander Pharmacy Scholarship Scheme is to encourage Aboriginal and Torres Strait Islander students to undertake undergraduate or graduate entry studies in pharmacy at an Australian University.</p> <p>Three undergraduate or post graduate Aboriginal and Torres Strait Islander Pharmacy scholarships of up to \$15,000 per annum are offered annually. The normal course length is four years (students can access up to \$60,000 over the period of their degree).</p>
Indigenous Health Services Pharmacy Support Program (IHSPS)	<p>The IHSPS Program supports services provided by Indigenous Health Services (IHSs) and Service Providers that contribute to the improvement of Quality Use of Medicines and health outcomes for Aboriginal and Torres Strait Islander people.</p>

6. Method and assumptions made in calculating the Regulatory Burden Estimates

Estimates are presented to provide an indication of the likely scale of the regulatory burden from policy proposals. These estimates are based on a number of assumptions (detailed below).

1. No regulatory burden is created for businesses, community organisations or individuals as a result of Commonwealth price changes for dispensing because the effort required to comply with the relevant obligations remains the same irrespective of the price point. The cost implications for government, business and individuals are therefore presented separately to the regulatory burden for each option.
2. Maintaining existing arrangements in relation to wholesaler mark-up and supply or the continuation of existing programs and associated requirements would not create additional regulatory burden. There is no additional effort required for businesses or to implement or meet the obligations if they maintain a similar approach.
3. The regulatory burden considerations are limited to those impacts which will result from each of the options presented for the remuneration of the supply of subsidised PBS medicines. This would include the potential negotiation of additional agreements by relevant stakeholders, particularly in relation to pharmacy programs but not the potential subsequent impacts that may occur as a result of such future negotiations or considerations.
4. Given stakeholder feedback to date there will be broad interest in contributing to the development agreements for pharmacy programs and their evaluation frameworks.
5. The below estimates were derived within the Department from knowledge of previous components of CPA negotiations.

Wholesaler remuneration (Option 1)

6. Wholesaler Remuneration is linked to the Commonwealth price, via the wholesale mark-up. The WMU can be viewed as a “pass-on” cost by pharmacies, as it is remuneration that is paid to wholesalers by the Commonwealth, through pharmacies. Changes to wholesaler remuneration would be negotiated with the peak body representative of wholesalers, the National Pharmaceutical Services Association (NPSA).
7. Assume a 3 month negotiation period including weekly meetings of 3 hours (based on current Guild meeting schedule).
8. An average 5 individuals from NSPA at a base rate work related labour cost of \$79.63/hour⁸⁰ would be involved in the negotiations for wholesaler remuneration.
9. Business impact = 12 weeks x 3 hours x 5 people x \$79.63 = \$14,333.40

⁸⁰ <https://oia.pmc.gov.au/resources/guidance-assessing-impacts/regulatory-burden-measurement-framework>

Pharmacy programs (Options 1 and 3)

10. There are 23 existing community pharmacy programs and approximately five more have been identified as priorities by stakeholders. This gives a total of 28 pharmacy programs to be considered.
11. An average of five key pharmacy sector stakeholder groups and two consumer groups, each including 3 individuals, would be involved in development of each program at a base rate work related labour cost of \$79.63/hour.
12. Assume an average 6 months of fortnightly meetings of 2 hours (based on current PSA meeting schedule).
13. Business impact = 28 programs x 13 weeks x 2 hours x 15 people x \$79.63 = \$869,559.60
14. Community Organisation impact – 28 programs x 13 weeks x 2 hours x 2 people x \$79.63 = \$115,941.28