Australian Government
Department of Health and Aged Care

Post-Implementation Review of the Seventh Community Pharmacy Agreement

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Purpose of the Post-Implementation Review

Australian Government agencies are required to undertake a Post-Implementation Review (PIR) in a number of situations, including when regulations that have impacts on businesses, community organisations or individuals, are introduced without a sufficient Regulation Impact Statement (RIS).

A PIR is required to examine:

- the problem the regulation was intended to address;
- the objective of government action;
- the impacts of the regulation; and
- the effectiveness of the regulation in meeting its objectives.

The overall goal of a PIR is to assess whether the regulation remains appropriate, and how effective and efficient it has been in meeting its objectives.

A PIR of the Seventh Community Pharmacy Agreement (7CPA) is required because a RIS was not finalised by the Department of Health and Aged Care and assessed by the Office of Best Practice Regulation (OBPR) before the signing of the 7CPA on 11 June 2020.

In accord with OBPR's direction, the Department undertook to complete a PIR of the 7CPA within two years of its implementation. This PIR is thus limited to activities undertaken under the 7CPA prior to 1 July 2022.

Executive Summary

The Seventh Community Pharmacy Agreement (7CPA) is a five-year agreement between the Commonwealth of Australia, The Pharmacy Guild of Australia (Guild), and the Pharmaceutical Society of Australia (PSA). The 7CPA commenced on 1 July 2020 and will continue until 30 June 2025.

The fundamental objective of the 7CPA is to ensure equitable access to Pharmaceutical Benefits Scheme (PBS) subsidised medicines for all Australians. Further, the 7CPA aimed to improve on the 6CPA in terms of greater access to community pharmacy programs; improving support for regional, rural and remote pharmacies; and improving access to medicines for Aboriginal and Torres Strait Islander people. Significantly, the 7CPA is the first agreement with the community pharmacy sector to include the PSA as a co-signatory alongside the Commonwealth and the Guild.

The 7CPA provides for an overall funding envelope of $18.35 billion, comprising:

- $16.00 billion in pharmacy remuneration for dispensing PBS subsidised medicines;
- $1.20 billion for professional pharmacy programs; and
- $1.15 billion for the Community Service Obligation and National Diabetes Services Scheme product distribution arrangements.

The 7CPA ensures all Australians will continue to have access to timely, safe, affordable, and life-saving medicines. It supports community pharmacy services to help achieve the best health outcomes for the Australian community. In the absence of Government intervention, the universal availability of PBS medicines and related services could not be assured, with those living in rural and remote areas most likely to experience distance barriers to access medicines through community pharmacies.

Supported by this Agreement, Australians are expected to access more than 200 million subsidised pharmaceutical prescriptions each year over the life of the Agreement.

This PIR provides an overview of the context in which Community Pharmacy Agreements (CPAs) have developed over time and an analysis of the impacts of specific changes made by the 7CPA in respect of pharmacy remuneration, wholesale supply and distribution arrangements, new and amended Community Pharmacy Programs and related services and activities supported under the Agreement.

Formal consultation arrangements under the 7CPA, centred around operation of the Community Pharmacy Consultation Committee (CPCC) and Pharmacy Stakeholder Consultation Committee (PSCC), which provide for more inclusive stakeholder consultation and participation, are also examined with regards to whether these arrangements are meeting agreed objectives and providing expected outcomes for stakeholders.

This review does not analyse the following issues:

- the negotiation process for the 7CPA;
- related activities and services supported by Government within the community pharmacy sector, including COVID-19 vaccinations, and the supply of concessional Rapid Antigen Tests, as they are outside of the scope of the 7CPA;

- market competition impacts, as these are unchanged from the Sixth Community Pharmacy Agreement (6CPA). Note that community pharmacy agreements have been in operation since 1990; and
- Pharmacy Location Rules, as the continuation of these was legislated during the term of the 6CPA with no change upon commencement of the 7CPA.

Stakeholder consultations undertaken as part of this PIR have provided valuable insight and observations of the impacts and expectations in relation to key aspects of the 7CPA.

As per previous CPAs, the 7CPA has been successful in centrally securing an agreement between Government and the community pharmacy sector providing benefits for Government in establishing defined pharmacy remuneration over 5 years, lending a level of certainty with respect to the cost of PBS medicines. In addition, the 7CPA provides business certainty for the continuation of remuneration for the dispensing of PBS medicines by approved pharmacists.

The 7CPA has provided a net benefit in terms of continuing to ensure access to medicines; increasing access to community pharmacy programs; providing better support for regional, rural and remote pharmacies; and improving access to medicines for Aboriginal and Torres Strait Islander people.

Key issues for the 7CPA, in common with previous CPAs, appear to be a lack of successful evaluation and assessment mechanisms in relation to the operation of programs and related activities funded through the agreement. In particular, the scarcity and quality of available data for robust and meaningful analysis of health outcomes is a continuing concern.

Aside from the recognised benefits of the 7CPA to the sector and the community, concerns have been raised amongst stakeholders regarding governance, transparency and accountability. A number of consulted stakeholders considered that in future alternatives to the current single agreement, encompassing pharmacy remuneration for the dispensing of PBS medicines as well as funding for the delivery of community pharmacy programs and related services, should be explored. However, this was outside the scope of this PIR.

This review concludes that the 7CPA is an appropriate mechanism for supporting arrangements for pharmacy remuneration, community pharmacy programs, and CSO funding pool arrangements and related services, consistent with previous CPAs.

Background

National Medicines Policy

Medicines in Australia are provided within the context of the *National Medicines Policy* (NMP)[1] which is a co-operative endeavour to bring about better health outcomes for all Australians, focussing on access to and quality use of medicines.

The NMP is a well-established and universally endorsed framework based on partnerships between Governments – Commonwealth, state and territory – health educators, health practitioners, other healthcare providers and suppliers, the medicines industry, healthcare consumers and the media working together to promote:

- quality care responsive to people’s needs;
- incentives for preventive health and cost-effective care;
- better value for taxpayers’ dollars;
- more clearly defined roles and responsibilities; and
- continued universal access to basic health services through Medicare.

The overall aim of the NMP is to meet medication and related service needs, so that both optimal health outcomes and economic objectives are achieved for individuals and the broader community.

The NMP has four central objectives based on active and respectful partnerships, taking into account elements of social and economic policy. These central objectives, also referred to as the four pillars of the NMP, are:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines; and
- maintaining a responsible and viable medicines industry.

The NMP functions within the context of wider public health strategies and policies including:

- The National Strategy for Quality Use of Medicines;
- The National Primary Health Care Strategic Framework;
- The National Preventative Health Strategy 2021-2030; and
- The National Health and Hospital Reforms.

A review of the NMP began in August 2021,[2] which will examine whether Australia’s NMP remains fit for purpose and relevant to the medicines landscape, now and into the future.

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[1] www.health.gov.au/resources/publications/national-medicines-policy
[2] www.pbs.gov.au/info/news/2021/06/national-medicines-policy-review-to-begin-in-august-2021

The Pharmaceutical Benefits Scheme

The Pharmaceutical Benefits Scheme (PBS) was initially established in 1948. It is an integral component of Australia's health system and forms part of the broader NMP. The PBS provides timely, reliable and affordable access to necessary medicines for Australians. Under the PBS, the Australian Government subsidises the cost of medicines for a range of medical conditions. Most PBS subsidised medicines are dispensed by community pharmacists and used by patients at home.

Through the PBS, the Government seeks to ensure the cost-effective delivery of medicines. Government investment in the PBS is significant, amounting to around 16 per cent of annual health expenditure and 0.7 per cent of gross domestic product in 2020-2021. Patient co-payments complement Government payments.

Consistent with the NMP, one of the objectives of the PBS is that all Australians should have equitable access to prescription medicines, regardless of where they live and at a price which they can afford. Because of the nature of the demographic and geographic distribution of the Australian population, some members of the community can have more difficulty than others in obtaining reasonable access to health services, including the supply of PBS medicines.

The PBS and its sister program targeted at eligible veterans, the Repatriation Pharmaceutical Benefits Scheme (RPBS), are primarily delivered through Australia's network of around 5,900 approved pharmacies.[3] The majority of government PBS/RPBS payments ($13.6 billion in 2020-2021[4]) are made to those pharmacies. The PBS and RPBS programs are intended to make prescribed medicines affordable and accessible for all Australians.[5]

As part of ensuring that the delivery of PBS services is efficient and equitable, the Government approves pharmacists to supply pharmaceutical benefits (i.e., to dispense PBS medicines) from specified pharmacy premises under section 90 of the *National Health Act 1953* (the Act). As part of that power of approval, the Government also approves where those pharmacies are physically located for the purpose of supplying PBS benefits.

Community pharmacy

Community pharmacy and pharmacists play a key role in primary health care in Australia through the delivery of 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;

[3] As at 30 June 2022, the number of pharmacies approved under section 90 of the *National Health Act 1953* to dispense PBS subsidised medicines was 5,901.
[4] *PBS Expenditure and Prescriptions Report 2020-21*; Available at: https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions-report-30-june-2021
[5] The PBS is available to all Australian residents who hold a current Medicare card. The RPBS can be accessed by veterans holding a DVA White, Gold or Orange Card.

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

Community pharmacies are often considered 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. On average, Australians visit a pharmacy 18 times a year, with pharmacies dispensing more than 200 million PBS prescriptions each year.[6]

In addition, Australia's community pharmacy network provides a mechanism for delivery of a range of broader health services to the community. Pharmacists employed in the community pharmacy sector deliver a range of government funded medication related services including medication reviews, dose administration aids and diabetes services, and provide professional advice to consumers on the safe and effective use of their medicines.

Community Pharmacy Agreements

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.[7] In the absence of the Government directly remunerating pharmacists for the supply and dispensing of PBS medicines to patients, separate arrangements would likely need to have been introduced for pharmacists to recover the costs of accessing PBS medicines for supply and for recovery of costs incurred in dispensing those medicines to patients.

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.[8] In 1981, the Pharmaceutical Benefits Remuneration Tribunal (PBRT) was established under section 98A of the Act and operates independently of Government to determine the Commonwealth price[9] paid to approved pharmacists for dispensing PBS subsidised medicines.

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[6] *Vital Facts on Community Pharmacy*, The Pharmacy Guild of Australia. Available at: https://www.guild.org.au/__data/assets/pdf_file/0017/115127/Vital-Facts-Sept2022.pdf
[7] C Sloane, *A History of the Pharmaceutical Benefits Scheme 1947–1992*, Australian Government Publishing Service, Canberra, 1995, pp. 52–59.
[8] 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.
[9] As defined under section 84 of the *National Health Act 1953*.

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.[10] The PBRT decided to change pharmacy remuneration by abolishing the 25% mark-up then applying to PBS medicines, and reducing the dispensing fee. The Guild opposed this decision. 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 Community Pharmacy Agreement (CPA). 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 other organisation representing a majority of community pharmacy owners approved to dispense PBS items.

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 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 enquiry 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"[11] which meant that if average prescription volumes decreased, the remuneration per prescription increased. This served as a disincentive for pursuing efficiencies through growth in pharmacy size; 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 enquiry noted that many areas had pharmacies located within 10 metres of each other, 25 per cent of pharmacies were within 100 metres of another pharmacy and 62 per cent were within 1 kilometre of another pharmacy.

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

[11] 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.

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 access ~~to~~ pharmacies, which made it difficult or expensive for consumers to access needed prescription medicines. This contributed 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 numbers of relatively inefficient pharmacies via the introduction of the Location Rules.

Second Community Pharmacy Agreement

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

This agreement 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) 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 of Health (Department), the Guild, and PSA. Administration of the Location Rules continued to be managed by the ACPA.

Fourth Community Pharmacy Agreement

The Fourth CPA (December 2005 – June 2010) continued remuneration and risk share arrangements from the Third CPA and made amendments to the Location Rules in respect of relocating pharmacies (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.

Significantly, the Fourth CPA also introduced the Community Service Obligation (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) 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) was a key element of the *PBS Access and Sustainability Package,*[12] 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*[13] (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 Community Pharmacy Programs; and $1.03 billion

[12] www.pbs.gov.au/info/general/pbs-access-sustainability-package
[13] www.anao.gov.au/work/performance-audit/administration-fifth-community-pharmacy-agreement

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.

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 and consultation with a broad range of stakeholders with a vested 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), 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 though 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 community pharmacy programs through the release of funding held in the Contingency Reserve, thus committing Government to delivering the full $1.26 billion allocated to programs funding 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).[14]

The Review of Pharmacy Remuneration and Regulation

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

[14] 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.

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

The Review's final report[15] 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 Community Pharmacy Agreement Processes.

The Government Response to the Review[16] was released by the 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 peoples regardless of where a prescription is written or dispensed;
  - transparency regarding the funding of community pharmacy programs;
  - 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,[17]

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[15] www1.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/$File/review-of-pharmacy-remuneration-and-regulation-final-report.pdf
[16] www1.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/$File/Pharmacy-Review-Aus-Gov-Response-3-May-2018.pdf
[17] 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.

  - 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 Community Pharmacy Agreements.

In making recommendations regarding future CPAs, the Review observed that:

> "The process for successive Community Pharmacy Agreements has evolved to a situation carrying a number of issues regarding transparency and sustainability for the future development of the sector."

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.

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 representative 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."

What problem was the 7CPA meant to solve?

The fundamental objective of successive Community Pharmacy Agreements (CPAs) has been to ensure equitable and affordable access to PBS medicines for all Australians through Australia's network of community pharmacies.

This is in keeping with the first pillar of the *National Medicines Policy* (NMP):[18] *timely access to the medicines that Australians need, at a cost individuals and the community can afford.*

To achieve this, an efficient and effective distribution and supply chain is required, particularly with respect to Australia's geographically dispersed population. As supported by successive CPAs, Australia's existing community pharmacy network continues to serve as the distribution system for PBS medicines in the community, with pharmaceutical wholesale distributors providing the supply chain to support this network.

Successive CPAs have thus seen Government reaching agreement with the Guild, as representing approved pharmacists, on the level of remuneration paid for dispensing PBS medicines. Additionally, through support payments to pharmaceutical wholesalers through CSO Funding Pool arrangements, these agreements have continued to support the equitable distribution of PBS medicines across Australia by pharmaceutical wholesalers. Successive CPAs have also continued to additionally support access to PBS medicines and pharmacy services for people living in rural areas by providing targeted financial support to eligible approved pharmacists in regional, rural and remote areas.

Centrally serving as a long-standing means of establishing with approved pharmacists the level of pharmacy remuneration for dispensing PBS medicines, CPAs have evolved over successive iterations to also include undertakings in relation to:

- funding for the delivery of a range of professional pharmacy programs in medication management and related services, supporting the safe and effective use of medicines for patients in the community; and
- support for the distribution of National Diabetes Services Scheme (NDSS) products through community pharmacy.

The appropriate remuneration of approved pharmacists for the supply and dispensing of PBS subsidised medicines thus continues to be a key component of supporting timely and efficient patient access to affordable medicines. As a new agreement between the Commonwealth and the Guild, the 7CPA formed the basis on which the level of remuneration paid by the Commonwealth to approved pharmacists for dispensing PBS medicines to patients would be determined.

In addition to continuing to support equitable and affordable access to PBS medicines, the 7CPA aimed to improve on the 6CPA in terms of:

- providing increased access to community pharmacy programs;
- providing better support for regional, rural and remote pharmacies; and
- improving access to medicines for Aboriginal and Torres Strait Islander people.

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[18] https://www.health.gov.au/resources/publications/national-medicines-policy

In making successive CPAs, both the Government and the Guild have continued to recognise broader policy intentions and common interests in:

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

In realising each of these outcomes as shared goals, CPAs have continued to be a preferred mechanism for both Government and the pharmacy sector in establishing pharmacy dispensing remuneration. CPAs have provided further benefits for Government in establishing defined pharmacy remuneration over 5 years, lending a level of certainty with respect to the cost of PBS medicines. In turn, CPAs have provided business certainty to the community pharmacy sector.

As such, the establishment of CPAs over the past 30 years reflects a partnership model, under which Government and the pharmacy sector work together to support Australians' access to PBS medicines and professional pharmacy services that support the safe and quality use of medicines.

In addition to the mutual reliance under this partnership model, there are also significant dependencies on other parts of the medicines supply chain, prescribers and other health care providers, digital and eHealth measures, workforce development and the different business models chosen by approved pharmacists as key enablers in supporting the role of pharmacists and the sustainability of the community pharmacy network. These each sit outside the scope of CPAs.

Notwithstanding the benefits to Government, the pharmacy sector and consumers from successive CPAs, Government increasingly faces the obligation to demonstrate accountability and greater transparency in the use of taxpayer funds. Thus, while continuing to negotiate successive CPAs with the Guild, as a representative of the majority of approved pharmacists, the Government has increasingly sought to also include consultation with a range of additional stakeholders across the pharmacy, pharmaceutical, hospital and health care sectors as well as consumer representative groups.

The 7CPA is then significant in being the first such agreement to include the PSA as a co-signatory, alongside the Guild. The 7CPA also introduces broader consultation arrangements, for the first time including the ongoing formal participation of consumer and Indigenous health representative bodies.

Why was government action needed?

The 6CPA expired on 30 June 2020. Under the terms of the 6CPA, the Government and the Guild had undertaken to commence negotiations for any new CPA twelve months prior to the expiry of the 6CPA, and to conclude negotiations by 31 March 2020.

As previously discussed, the remuneration of approved pharmacists for the supply and dispensing of PBS subsidised medicines is a key component of supporting timely and efficient patient access to affordable medicines and continues to be a vital component in the Government's continued delivery of the PBS.

Successive CPAs have, in addition, continued to support the equitable distribution of PBS medicines across Australia through CSO Funding Pool payments to pharmaceutical wholesalers as well as supporting access to PBS medicines and pharmacy services for people living in rural areas through targeted financial support to eligible approved pharmacists in regional, rural and remote areas.

In the absence of this level of intervention in the pharmacy marketplace the universal availability of PBS medicines within the community could not be assured, with people living in rural and remote areas most likely to experience distance barriers to access to community pharmacies. This would make it difficult or expensive for consumers to access needed prescription medicines and result in poorer health outcomes for Australians living in rural and remote areas than for those living in urban or near-urban areas.[19]

Taken as a means of simply continuing the operation of existing market support arrangements, the negotiation of a new (seventh) CPA (7CPA) provided an opportunity for Government to maintain its ongoing partnership with the community pharmacy and pharmaceutical supply-chain sectors to provide Australians with a guarantee of continued access to PBS medicines and related services.

In the absence of there being an agreement in place by which an appropriate level of remuneration to pharmacists for dispensing PBS medicines were agreed, pharmacist remuneration would be independently determined by the Pharmaceutical Benefits Remuneration Tribunal (PBRT) – as had been the case for nine years prior to commencement of the first CPA in December 1990.

Whereas pharmacist remuneration would thus continue, all other activities supported under the 6CPA would have ceased in the absence of alternate arrangements being made. This would include:

- CSO Funding Pool arrangements providing support payments to pharmaceutical wholesalers for the equitable supply and distribution of PBS medicines across Australia;
- Rural Pharmacy Maintenance Allowance payments to eligible approved pharmacists in regional, rural and remote areas, supporting access to PBS medicines and pharmacy services for Australians living in rural areas;

[19] http://ruralhealth.org.au/sites/default/files/documents/nrha-policy-document/policy-development/nrha-medicines-discussion-paper-january-2014.pdf

- Funding for community pharmacy programs, including medication review services and medication management and adherence programs to assist Australians to manage their medicines; and
- NDSS product distribution arrangements, supporting access to NDSS products and services for patients living with diabetes through their community pharmacy, wherever they live in Australia.

A key issue in not continuing to have a CPA would likely be a level of drop-off in business confidence and investment across the community pharmacy and pharmaceutical supply sectors in moving away from the certainty of a five-year agreement with Government on remuneration and other supported activities.

In the absence of there being a formal agreement between the Commonwealth and the community pharmacy sector, any additional benefits foreseen in negotiating a 7CPA could not be expected to be achieved with any level of certainty.

Key advantages of the new CPA included:[20]

- Government continuing to partner with community pharmacy to ensure continued access for Australians to more than 200 million PBS prescriptions per year;
- increased investment in medication management services and programs providing consumers access to advice about the quality use of medicines;
- ensuring Australians have access to consumer-focussed community pharmacy programs;
- greater support for regional, rural and remote pharmacies to deliver community pharmacy services through reforms to the Rural Pharmacy Maintenance Allowance;
- improving access to medicines for Aboriginal and Torres Strait Islander people; and
- greater funding predictability for the dispensing of PBS medicines by community pharmacies through structural reforms to dispensing remuneration, and risk sharing arrangements.

[20] www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/more-essential-support-for-australian-patients-through-community-pharmacy

What policy options were considered?

In early 2019, Government committed to the expedited negotiation of a new Agreement with the community pharmacy sector[21] and to include the PSA as a signatory for the first time.[22]

Other options considered by Government in relation to the expiry of the 6CPA on 30 June 2020, with varying degrees of weight compared to the preferred option, were:

- Extending the 6CPA beyond 30 June 2020; or
- Taking no action.

Establishing a new five-year 7CPA (preferred)

This option maintained the status quo of continuing to have a CPA in place. This required negotiating and reaching agreement with the Guild and PSA on the terms and conditions of a new 7CPA to commence from 1 July 2020.

In establishing a 7CPA, activities supported under the 6CPA would be continued, including:

- pharmacy dispensing remuneration;
- CSO Funding Pool payments to pharmaceutical wholesalers;
- rural pharmacy support payments;
- NDSS distribution arrangements; and
- funding for professional pharmacy programs.

Further, reaching agreement on a 7CPA provided opportunity to realise additional benefits including:

- increased government investment in professional pharmacy programs aimed at supporting the quality use of medicines, including the safe and effective use of medicines;
- increased government investment, program reform and increased access to PBS medicines and related services for Aboriginal and Torres Strait Islander people and older Australians;
- increased support for the rural and remote pharmacy network including equitable distribution of pharmacies;
- 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;
- a stringent risk-share mechanism to provide certainty and predictability for Government and the pharmacy sector for PBS dispensing remuneration;

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[21] *Continued support for Australia's community pharmacies*, 7 March 2019. Media release available at: www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/continued-support-for-australias-community-pharmacies

[22] *Minister Hunt Commits to PSA being a signatory to 7CPA,* Australian Pharmacist, 13 February 2019. Available at: www.australianpharmacist.com.au/psa-sign-7cpa/

- increased transparency and affordability in relation to allowable patient charges for dispensed PBS medicines;
- broader access to vaccination services through a nationally consistent approach for vaccination access through community pharmacy; and
- improved agreement consultation and governance arrangements.

In recognition of the Government's objective of improved and more transparent governance arrangements for activities funded under a new CPA, the PSA was included as an additional signatory to the 7CPA, supporting broader engagement on the future development and delivery of professional pharmacy services funded under the Agreement.

As such, agreement to a 7CPA would continue to support Australian patients with timely, safe and affordable access to over 200 million subsidised PBS scripts each year and valuable medication related services through Australia's network of community pharmacies.

Government's preferred option was to establish a new 7CPA by 30 June 2020.

Extending the 6CPA beyond 30 June 2020

This option would have required the Commonwealth negotiating and reaching agreement with the Guild, as co-signatory of the 6CPA, to extend the 6CPA for an agreed period of time. This option would have continued all arrangements under the 6CPA in relation to: pharmacy dispensing remuneration; CSO payments to pharmaceutical wholesalers: rural pharmacy support payments; NDSS product distribution arrangements; and funding for professional pharmacy programs.

Ultimately, this option was not preferred by Government, in favour of negotiating improved outcomes for patients, the community pharmacy sector and Government under a new 7CPA. Similarly, the Guild supported negotiation of a new 7CPA.

Taking no action

Following expiry of the 6CPA on 30 June 2020, in taking no action there would have been no formal agreement in place between the Commonwealth and the community pharmacy sector regarding pharmacy dispensing remuneration and related activities.

In the absence of a CPA, the PBRT would independently determine the Commonwealth price by which pharmacy dispensing remuneration would continue. Specifically, the then current *Commonwealth Price (Pharmaceutical Benefits Supplied by Approved Pharmacists) Determination 2015* separately provided that pharmacy dispensing remuneration to approved pharmacists would have continued at the rate operating in the final year of the 6CPA.

In this case, the PBRT would also independently determine the frequency with which pharmacy remuneration were to be determined.[23]

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[23] Section 98BA of the *National Health Act 1953 (Cth)* provides that, in the absence of there being an agreement between the Commonwealth and the community pharmacy sector on pharmacy remuneration, the Chair of the PBRT will decide the frequency with which the PBRT would determine the Commonwealth price.

Further, separate arrangements would need to be established for funding of other activities including: CSO payments to pharmaceutical wholesalers, rural pharmacy support payments, NDSS product distribution, as well as for continued funding of professional pharmacy programs to support patient medication management and the safe and effective use of medicines within the community. Each of these activities, funded under the 6CPA, would otherwise cease upon expiry of the 6CPA without an alternative funding source.

As outlined above, this option was not preferred by Government.

What have been the impacts of the 7CPA?

The 7CPA commenced on 1 July 2020 and will operate until 30 June 2025. The 7CPA provides for an overall funding envelope of $18.35 billion, comprising:

- $16.00 billion in pharmacy remuneration for dispensing PBS subsidised medicines (Commonwealth and patient contributions);
- $1.20 billion for professional pharmacy programs;
- $1.15 billion for the CSO and NDSS product distribution arrangements.

In comparison to the 6CPA, the 7CPA provided increased investment in community pharmacy remuneration for dispensing, pharmacy programs, and CSO and NDSS distribution arrangements.

Table 1. Comparative funding under 6CPA and 7CPA – estimated actual expenditure under 6CPA vs indicative maximum allocations under 7CPA.

Components of CPA funding	6CPA ($m)	7CPA ($m)
Dispensing remuneration (above PBS co-payment items) *(Commonwealth and patient contributions)*	$14,713	$16,000
Community Pharmacy Programs funding	$1,102	$1,200
CSO funding	$991	$1,083
NDSS product distribution fees	$45	$66
Total CPA funding	***$16,851***	***$18,349***

The 7CPA has continued activities previously supported under the 6CPA, with increased investment by Government, supporting increased benefits for consumers, as well as the pharmacy sector.

Specifically, the 7CPA has brought key changes to previous arrangements with respect to:

- *Pharmacy remuneration structures and levels* – to provide rebased values and growth rates to support ongoing remuneration over the course of the 7CPA;
- *Wholesaler remuneration arrangements* – to make adjustments to wholesaler mark-up arrangements, including introduction of a minimum wholesaler mark-up floor price per PBS item supplied, and providing additional investment into the CSO Funding Pool;
- *Community Pharmacy Programs* – to deliver an ongoing investment in a range of pharmacy services aimed at supporting the quality use of medicines, including the safe and effective use of medicines; and
- *Consultation arrangements* – to provide a more inclusive level of representation across stakeholder groups in addition to the pharmacy sector.

The 7CPA continues to support broadening consumers' access to vaccinations through community pharmacy. Specifically, the 7CPA commits Government to supporting the adoption of a nationally consistent approach in respect of vaccines that may be administered by appropriately trained registered pharmacists.[24]

During the term of the 6CPA, Government legislated to ensure the continuation of Location Rules. The 7CPA includes an undertaking that Government has no plan to change the Location Rules during the term of the 7CPA and will consult with the Guild prior to any changes being made.[25]

In addition, the optional $1 discount on PBS patient co-payments, introduced in legislation[26] during the term of the 6CPA, continues independently of the 7CPA. This promotes competition amongst pharmacies and ensures that patients will continue to access more affordable medicines through reduced out-of-pocket costs.

Parties benefiting from these arrangements under the 7CPA have been:

- community pharmacies in relation to remuneration for supply of PBS medicines and the delivery of pharmacy programs;
- pharmaceutical wholesalers, including those participating in the CSO Funding Pool arrangements; and
- consumers, in relation to maintenance of the cost of PBS medicines from approved pharmacies, access to a network of geographically dispersed community pharmacies, and eligible members of the public, in relation to continued or increased access to pharmacy programs and services.

Impact on PBS dispensing and remuneration

The 7CPA has continued to support effective and efficient access to PBS and RPBS medicines to the community, with increases in prescription volumes and expenditure since its commencement.

The key changes from 6CPA to 7CPA in terms of dispensing were:

- From 1 July 2020 dispensing fees were increased and simplified to provide greater predictability for community pharmacy and ensure the safe supply of medicine for patients.
- At the same time, the level of allowable discretionary fees charged by pharmacists for PBS medicines that are not subsidised by the Commonwealth and priced below the general PBS patient co-payment, was reduced by 21 cents per script under the 7CPA.

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[24] Clause 12.2 of the 7CPA.
[25] Clause 12.3 of the 7CPA
[26] Section 87 of the *National Health Act 1953*.

- In addition, 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.[27]
- In recognition of the need to continue to ensure the safe dispensing of 'Schedule 8' drugs[28] (aka drugs of addiction), the 7CPA introduced an increase to the Dangerous Drug Fee paid by Government, from $3.01 to $4.80 per eligible dispense.
- In recognition of the widespread use of generic brands of medicines within the industry and community, the Premium Free Dispensing Incentive Fee, paid under the 6CPA, was ceased on commencement of the 7CPA, with redirection of related funding into remuneration for dispensing of medicines.
- For the first time the 7CPA also introduced a stringent risk-sharing arrangement, as a volume-based Remuneration Adjustment Mechanism (RAM),[29] to provide greater certainty for Government, and predictability for community pharmacy.

PBS Prescription Volumes

As indicated in Table 2 below, the total volume of PBS prescriptions dispensed through community pharmacies in the first year of the 7CPA (1 July 2020 – 30 June 2021) was 0.8% greater than for the final year of the 6CPA (1 July 2019 – 30 June 2020). This represents a real increase in volume (for PBS items) on the basis of being greater than that of Australia's general population growth over the first year of the 7CPA, which was 0.13% in the 12 months to 30 June 2021.[30]

Table 2. Volume of PBS subsidised prescriptions dispensed by community pharmacies in last year of 6CPA vs first year of 7CPA.[31] *Section 85 and section 100, including Drs Bag and under co-payment prescriptions.*

Prescription type	1 July 2019 – 30 June 2020 (6CPA)	1 July 2020 – 30 June 2021 (7CPA)	Percentage Change
Concessional patients	190,115,741	194,841,386	2.5%
General Patients	17,947,964	18,336,213	2.3%
Drs Bag	418,651	360,456	-13.9%
Under Co-payment	96,378,870	93,590,025	-2.9%
Total	***304,861,226***	***307,158,080***	***0.8%***

Whereas it may be assumed that the proportion of the population using PBS medicines will increase in response to increased medicines use as the population ages, any observed

[27] Clause 4.3 of the 7CPA.

[28] Schedule 8 of the *Poisons Standard (Cwlth)* pertains to Controlled Drugs as: "Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence."

[29] By this process, should PBS subsidised script volumes be materially lower than an agreed estimate in any assessment period, an increase to remuneration can be made via a supplement to the Administration Handling and Infrastructure fee component of the Commonwealth price paid to pharmacists. Conversely, if the actual subsidised script volumes are higher (by more than 5 per cent) than estimated in any assessment period, a reduction in per-script remuneration can be made via the same mechanism.

[30] Based on ABS Australian population statistics available from: www.abs.gov.au/statistics/people/population/national-state-and-territory-population/latest-release

[31] Data source: *PBS Expenditure and Prescriptions Reports 1 July 2019 to 30 June 2020* and *1 July 2020 to 30 June 2021*: www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions

increase in PBS script volume in the first year of the 7CPA would more likely be due to a complex interplay of a number of factors. The instance of natural disasters, including bushfires and floods, affecting medicines use as well as responses to the emerging COVID-19 pandemic may also be significant contributing factors to increased prescription growth during this time. Changes made during the COVID-19 pandemic to support access to medicines for people during lock-down and quarantine, including telehealth medical consultations, electronic medicines prescriptions, the PBS Continued Dispensing Emergency Measure and the Home Medicines Service may also have had effect on PBS volume growth in the first year of the 7CPA. Moreover, the data in Table 2 primarily confirm that the 7CPA is meeting the objective of continuing to support access to PBS medicines in the community.

PBS Dispensing Remuneration

Pharmacy remuneration recognises the cost to pharmacist for the purchase of PBS medicines (comprising Approved Ex-Manufacturer Price (AEMP)[32] plus wholesale mark-up); the administration, handling and storage costs entailed in dispensing medicines by the pharmacy (including associated infrastructure costs); and a pharmacist's specialised skills in dispensing the medicines (comprising a dispensing fee and other relevant fees).

On a per-script basis, pharmacy dispensing remuneration was increased on commencement of the 7CPA and will increase annually over the life of the Agreement. Table 3, below, compares the amounts by which pharmacy remuneration will increase (based on agreed increases to the Administration Handling and Infrastructure (AHI) Fee and Dispensing Fee) in each year of the 7CPA against increases that would have applied if the Consumer Price Index (CPI) had been used to determine increases in every year of the 7CPA, as detailed in Clause 13 of the 7CPA for years 4 and 5 only. Whereas dispensing remuneration was thus indexed by a fixed amount of 0.5% at the start of the second and third years of the 7CPA, increases at the start of the fourth and fifth years will be made on the basis of CPI. As such,

[32] Approved Ex-Manufacturer Price (AEMP), as agreed between government and manufacturer, is the price charged by the manufacturer for medicines listed on the Pharmaceutical Benefits Scheme.

Table 3. Year on year increase in per-script pharmacy remuneration under 7CPA vs Consumer Price Index (CPI).

Date	Based on 7CPA indexation (%)[a]	Based on CPI for quarter to 30 June immediately prior (%)[d]
1 July 2020 *(Year 1)*	4.7[b]	2.2
1 July 2021 *(Year 2)*	0.5[c]	1.1
1 July 2022 *(Year 3)*	0.5[c]	5.1
1 July 2023 *(Year 4)*	*to be based on CPI*[c]	*as for 7CPA*
1 July 2024 *(Year 5)*	*to be based on CPI*[c]	*as for 7CPA*

[a] *Pharmacy dispensing remuneration is the sum of the AHI Fee and a Dispensing Fee, each of which are subject to annual indexation.*

[b] *increase relative to last year of 6CPA, based on an increase in AHI fee (for a PBS medicine priced below $100) from $4.09 to $4.28 and an increase in Dispensing Fee (for Ready-Prepared Pharmaceutical Benefits) from $7.39 to $7.74.*

[c] *Clause 13 of the 7CPA.*

[d] *source: www.abs.gov.au/statistics/economy/price-indexes-and-inflation/consumer-price-index-australia/mar-2022*

pharmacy remuneration under 7CPA can be expected to see significant increases from the fourth year of the 7CPA, in step with expected future rises in CPI.

Table 4 presents a comparison of Government expenditure on pharmacy remuneration for PBS subsided medicines through community pharmacy for the final year of 6CPA and the first year of 7CPA.

Table 4. Renumeration for community pharmacies for dispensing PBS subsidised prescriptions in last year of 6CPA vs first year of 7CPA.[33] *Section 85 and section 100, including Drs Bag, excluding under co-payment prescriptions.*

[33] Data source: *PBS Expenditure and Prescriptions Report 1 July 2020 to 30 June 2021*: www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions-report-30-june-2021

Remuneration component	1 July 2019 – 30 June 2020 (6CPA)	1 July 2020 – 30 June 2021 (7CPA)	Percentage change
Ex-Manufacturer Price	$6,962,682,865	$7,362,814,544	5.8%
Wholesale Mark-up	$409,523,060	$425,185,142	3.8%
Sub-total *(price to pharmacist)*	***$7,372,205,925***	***$7,787,999,685***	***5.6%***
Administration Handling and Infrastructure fee	$990,743,919	$1,125,735,385	13.6%
Dispensing Fee	$1,557,293,775	$1,669,577,633	7.2%
Dangerous Drug Fee	$25,569,359	$40,634,218	58.9%
Wastage	$3,137,198	$4,292,312	36.8%
Container Fee	$666,944	$1,415,592	112.3%
Premium Free Dispensing Incentive Fee *	$157,944,399	$0	*-100%*
Electronic Prescription Fee	$13,455,626	$14,877,612	10.6%
Sub-total *(pharmacy cost)*	***$2,748,811,220***	***$2,856,532,729***	***3.9%***
Total	***$10,121,017,146***	***$10,644,532,438***	***5.2%***

** The Premium Free Dispensing Incentive was discontinued under the 7CPA from 1 July 2020.*

Whereas the total cost to pharmacist of PBS medicines dispensed through community pharmacies showed an increase of 5.6% between the last year of 6CPA and first year of 7CPA, the pharmacist remuneration component of PBS Expenditure increased by only 3.9%, largely due to discontinuation of the Premium Free Dispensing Incentive Fee on commencement of the 7CPA, which had itself accounted for almost $158 million in PBS expenditure in the last year of 6CPA. As discussed above, pharmacy remuneration per prescription will increase each year under the 7CPA and can be expected to see significant increases from the fourth year of the 7CPA, when indexation is directly linked to CPI.

Impact on wholesaler remuneration arrangements

Agreed reforms address PBS medicines distribution concerns raised by stakeholders in consultations and reviews conducted during the 6CPA,[34] and in negotiations of the 7CPA:

- The CSO for pharmaceutical wholesalers has continued under the 7CPA, with increased investment in the CSO funding pool of up to $1.083 billion over five years, providing support to eligible wholesalers for the timely and affordable supply of PBS medicines and related products across Australia.
- In addition, the existing tiered mark-up arrangements for pharmaceutical wholesalers were restructured under the 7CPA from 1 January 2021, with the introduction of a

[34] www1.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/$File/interim-report-final.pdf

wholesale mark-up floor price of 41 cents, per item supplied, for the supply of low-cost PBS and RPBS medicines priced at or below $5.50 (AEMP).

The 7CPA thus ensures funding sustainability and stability through increased funding for pharmaceutical wholesaler activities that support timely, affordable and equitable access to PBS medicines, NDSS products and other targeted health aids and appliances for patients via community pharmacy regardless of where they live.

Impact on Community Pharmacy Programs

The 7CPA has continued to support the delivery of consumer-focused community pharmacy programs and related services within the community and the introduction of new Indigenous Pharmacy Programs providing improved access for Aboriginal and Torres Strait Islander people. From 1 July 2020, the 7CPA provided an increase in funding for Community Pharmacy Programs delivering an additional $100 million over five years, compared to expenditure under the 6CPA.

Professional pharmacy programs from the 6CPA which have continued under the 7CPA include:

- Dose Administration Aids (DAA);
- Staged Supply;
- Home Medicines Reviews (HMR);
- MedsCheck and Diabetes MedsCheck;
- Residential Medication Management Reviews (RMMR) and Quality Use of Medicines;
- a range of rural workforce and training allowances;
- Quality Use of Medicines Maximised for Aboriginal and Torres Strait Islander People (QUMAX);
- S100 Pharmacy Support Allowance; and
- a range of Aboriginal and Torres Strait Islander workforce schemes.

These programs have been, and continue to be, improved and reprioritised under the 7CPA with a focus on being simplified for pharmacists and increasing the number of services for patients within the existing funding envelope.

Table 5 below presents the total expenditure and number of services delivered for community pharmacy programs continuing from the last eighteen months of 6CPA (1 January 2019 – 30 June 2020) to the first eighteen months of 7CPA (1 July 2020 – 30 December 2021). With the exception of QUM in residential Aged Care Facilities, for which data was not available under the 6CPA, increases in the number of services delivered have been seen for all programs continued from the 6CPA to the 7CPA.

Table 5. Expenditure and number of services delivered for Community Pharmacy Programs, continuing from 6CPA to 7CPA.

	1 Jan 2019 – 30 Jun 2020 (6CPA)			1 Jul 2020 – 31 Dec 2021 (7CPA)			Increase in services	Change in cost per service
Program	Expenditure	Services	Cost per service	Expenditure	Services	Cost per service		
Dose Administration Aids	$138,523,353	23,326,731	$5.94	$146,480,688	23,684,947	$6.18	1.5%	4.04%
Staged Supply	$11,930,742	236,448	$50.45	$13,434,060	280,318	$47.92	18.5%	-5.01%
Home Medicines Reviews	$28,747,141	1,369,76	$209.87	$35,445,298	179,903	$197.02	31.3%	-6.1%
Residential Medication Management Reviews	$18,334,068	182,826	$100.28	$20,976,768	206,843	$101.41	13.1%	1.12%
MedsCheck and Diabetes MedsCheck	$67,283,719	783,412	$85.88	$61,322,244	816,744	$75.08	4.3%	-12.57%
QUM in Residential Aged Care Facilities [a]	–	–		$17,022,136	2859[b]	$5953.88	–	
QUMAX [c]	$2,467,278[d]	83[b,d]	$29,726.24	$ 2,476,807[e]	84[b,e]	$29,485.80	1.2%	-0.81%
S100 Support [c,d]	$1,943,632[d]	23[b,d]	$84,505.74	$2,236,375[e]	25[b,e]	$89,455	8.7%	5.86%

[a] *data was not available for number services and expenditure for this program under 6CPA.*

[b] *average number of participating facilities.*

[c] *QUMAX and S100 support programs were transitioned to the new IHSPS Program from 1 July 2021.*

[d] *data is presented for period from 1 July 2019 – 30 June 2020.*

[e] *data is presented for period from 1 July 2020 – 30 September 2021.*

Whereas increases in expenditure per service are seen for Dose Administration Aids, Residential Medication Management Reviews, and S100 Support Programs from 6CPA to 7CPA, decreases are observed for Staged Supply, Home Medicines Review, MedsCheck and Diabetes MedsCheck, and QUMAX programs, as a result of fee reduction for these programs under the 7CPA, potentially driving any efficiency gains.

Support for Aboriginal and Torres Strait Islander peoples

Program reforms have been implemented under the 7CPA to provide improved access to medicines to Aboriginal and Torres Strait Islander peoples, including:

- reform of the *Closing The Gap PBS Co-payment Program* – commenced from 1 July 2021 enabling Aboriginal and Torres Strait Islander patients to utilise these arrangements wherever they live and whatever their chronic disease status;
- introduction of an *Indigenous Dose Administration Aids* (IDAA) program, from 1 July 2021, to increase access to culturally appropriate services and medication adherence enabling more Aboriginal and Torres Strait Islander patients to access an uncapped number of Dose Administration Aids with no patient payment;
- *Indigenous Health Services Pharmacy Support* (IHSPS) program – introduced from 1 July 2021, this program supports quality use of medicines (QUM) services and aims to improve QUM and health outcomes for Aboriginal and Torres Strait Islander peoples by providing funding for the purchase of a range of QUM Support activities by eligible Indigenous Health Services.

Table 6 presents information on the uptake of new and revised Indigenous Pharmacy Programs under the 7CPA. For each of these programs there has been strong uptake since commencement with significantly increased numbers of prescriptions dispensing under the CTG PBS Co-payment Program following program changes from 1 July 2021.

Table 6. Services and expenditure for new and amended Indigenous Community Pharmacy Programs under the 7CPA.[a]

	1 Jul – 31 Dec 2020		1 Jan – 30 Jun 2021		1 Jul – 31 Dec 2021	
Program	**Items [b]**	**Expenditure**	**Items [b]**	**Expenditure**	**Items [b]**	**Expenditure**
IDAA [c]	–	–	–	–	635,108	$7,433,675
IHSPS [c]	–	–	–	–	225	$1,958,321
CTG Co-payment [d]	3,775,702	$24,313,491	3,782,231	$31,510,276	4,417,782	$29,305,252

[a] *Data source: 7CPA Rural Support and Aboriginal and Torres Strait Islander Pharmacy Programs data*
[b] *IDAA & IHSPS = services provided; CTG = PBS items supplied.*
[c] *IDAA & IHSPS Programs commenced 1 July 2021.*
[d] *Changes to CTG Co-payment Program were introduced on 1 July 2021.*

Table 7 below indicates that the number of unique patients accessing the CTG PBS Co-payment program had increased by over 70,000 in the 12 months since the introduction of program changes. This compares to annual increases of the order of 1,000 patients under previous program arrangements.

Table 7. Services, patient numbers and expenditure under CTG PBS Co-payment program pre and post 1 July 2021 program enhancements under 7CPA.

Period	Annual Expenditure	PBS Prescriptions	Patients
1 July 2019 – 30 June 2020	$54,509,667	7,225,985	385,682
1 July 2020 – 30 June 2021	$55,863,581	7,561,274	396,899
1 July 2021 – 30 June 2022[a]	$67,410,689	8,769,513	469,310

[a] Changes to the CTG PBS Co-payment Program came into effect 1 July 2021
Information obtained from PBS online claims data maintained by the Department of Health and Aged Care and sourced from Services Australia. Data extracted 24 August 2022.

Support for rural and remote pharmacy network including equitable distribution

Under the 7CPA, funding for the Rural Pharmacy Maintenance Allowance (RPMA) program[35] was increased. Continuing from the 6CPA, the RPMA program provides allowance payments to approved pharmacists in rural and remote locations with lower prescription volumes to support continued consumer access to PBS and RPBS medicines and pharmacy services in these locations.

From 1 January 2021, in accord with arrangements agreed under the 7CPA, RPMA eligibility and payment values were transitioned from the previous use of Pharmacy Accessibility/Remoteness Index of Australia (PhARIA) categories to be based upon the Modified Monash Model (MMM) rural classification system.

Table 8 below provides comparative information on RPMA payments provided to approved pharmacists under 6CPA and 7CPA. With the transition of pharmacy eligibility criteria from PhARIA to the MMM system during the first year of 7CPA, the number of eligible approved pharmacists receiving RPMA support payments from 1 January 2021 increased by 241 in areas ranging from large rural towns (MMM3) to very remote communities (MMM7). Notwithstanding, 22 approved pharmacists, previously in PhARIA categories 2 and 3 which were reclassified under the new arrangements to MMM 2[36] became ineligible to receive RPMA support payments.

As an ongoing support payment scheme for approved pharmacists in regional, rural and remote areas the RPMA program has continued under 7CPA to support access to PBS medicines for people living in rural and remote areas.

[35] Operating as the Regional Pharmacy Maintenance Allowance (RPMA) from 1 January 2021 under the 7CPA.
[36] MMM2 inner and outer regional centres in or within a 20km drive of a town with over 50,000 residents.

Table 8. Approved pharmacies receiving RPMA payments in last year of 6CPA vs first year of 7CPA.

	6CPA (1 July 2019 – 30 June 2020)		7CPA (1 July 2020 – 30 June 2021)*	
Remoteness Index	**Number of Pharmacies**	**Expenditure**	**Number of Pharmacies**	**Expenditure***
PhARIA 2	140	$1,215,554	141	$658,668
PhARIA 3	303	$3,509,658	303	$1,903,124
PhARIA 4	142	$2,581,749	144	$1,395,487
PhARIA 5	144	$4,348,907	151	$2,268,158
PhARIA 6	93	$3,840,687	87	$1,877,649
Total	***822***	***$15,496,556***	***826***	***$8,103,089***
MMM 3	0	$0	221	$290,250
MMM 4	0	$0	203	$997,122
MMM 5	0	$0	496	$5,421,613
MMM 6	0	$0	91	$1,612,230
MMM 7	0	$0	56	$1,363,191
Total	***0***	***$0***	***1067***	***$9,684,407***
Annual Expenditure		***$15,496,556***		***$17,787,496***

** Pharmacy eligibility for RPMA payments was based on PhARIA system of rural classification from 1 July 2020 to 31 December 2020 and on the MMM classification system from 1 January 2021 – 30 June 2021.*

Impact on consultation arrangements

Under the 7CPA a more inclusive consultation structure has been implemented whereby the single Agreement Oversight Committee previously operating under the 6CPA has been replaced by two formal consultation committees providing broader and more inclusive consultation in relation to operation of the 7CPA.

The Community Pharmacy Consultation Committee (CPCC) is composed of up to three members appointed by the Department and up to three members appointed by the Guild and chaired on an alternating basis by a senior member of the Department or Guild. The CPCC meets up to two times a year to enable the Commonwealth and Guild to consult on matters relating to pharmacy dispensing remuneration as they relate to the Commonwealth price.

The Pharmacy Stakeholder Consultation Committee (PSCC) includes the Department, the Guild and PSA as standing members. The National Aboriginal Community Controlled Health Organisation (NACCHO) and Consumers Health Forum of Australia (CHF) are also represented at the invitation of the Department. The PSCC meets up to two times a year to consult on a range of matters relevant to activities under the 7CPA other than pharmacy dispensing remuneration. The PSCC is chaired by a senior representative of the Department or, where the PSCC would consider matters predominantly related to Aboriginal and Torres Strait Islander peoples, a representative of that community.

Impact on access to community pharmacy

While the number of approved pharmacists increased year on year over the 6CPA the ratio of approved pharmacists in urban versus rural areas has shown little variation over this time. Table 9 below indicates the number and proportion of PBS approved pharmacists in urban (PhARIA 1) and rural (PhARIA 2-6) areas of Australia as at 30 June for the years 2015 – 2021.

Table. 9. PBS approved pharmacists in urban and rural areas as at 30 June 2015 – 2021.[37]

Year	No. in Urban	No. in Rural	% Urban	% Rural
2021	4,962	913	84.46%	15.54%
2020	4,924	898	84.58%	15.42%
2019	4,879	883	84.68%	15.32%
2018	4,782	941	83.56%	16.44%
2017	4,733	932	83.55%	16.45%
2016	4,679	909	83.73%	16.27%
2015	4,620	891	83.83%	16.17%

Table 10 below presents a comparison of pharmacy numbers and PBS prescription volumes for approved pharmacists by PhARIA designation for the last year of 6CPA and first year of 7CPA. Population growth considerations aside, the most significant increase in PBS script volume was observed for pharmacies in PhARIA 2 (rural, 2.75%), with pharmacies in PhARIAs 3 – 6 (rural – very remote) consistently exhibiting increases of up to 2%. For pharmacies in PhARIA 1 (highly accessible) a marginal decrease in script volume (-0.03%) was observed. The observed changes in script volumes may be reflective of charges in population distribution in response to an increased move to remote working arrangements during the COVID-19 pandemic from early 2020 onwards.

[37] Source: *Report on Government Services 2022*. Available at: www.pc.gov.au/ongoing/report-on-government-services/2022/health/primary-and-community-health

Table 10. PBS Script volumes and number of PBS approved pharmacies by PhARIA dispensing PBS items in 2019-20 and 2020-21.[38] *Section 85 and section 100, including Drs Bag and under co-payment prescriptions.*

	1 July 2019 – 30 June 2020 (6CPA)		1 July 2020 – 30 June 2021 (7CPA)		% change 6CPA – 7CPA	
PhARIA	**Pharmacies**	**Scripts**	**Pharmacies**	**Scripts**	**Pharmacies**	**Scripts**
1	5,324	263,648,693	5,298	263,577,357	-0.49%	-0.03%
2	181	9,410,175	195	9,669,403	7.73%	2.75%
3	368	15,378,296	365	15,676,064	-0.82%	-1.94%
4	151	5,115,533	155	5,186,661	2.65%	1.39%
5	154	3,896,849	167	3,962,819	8.44%	1.69%
6	99	1,742,943	97	1,774,427	-2.06%	-1.81%
unass.*	(36)	(641,972)	(62)	(2,222,456)	–	–
Totals	***6,313****	***299,834,461***	***6,339****	***302,069,187***	***0.41%***	***0.75%***

** Pharmacies for which PhARIA was unassigned.*
*** these totals represent the number of unique individual PBS approved pharmacies having dispensed PBS items during each year and do not represent the total number of PBS approved pharmacies at any one time.*

With respect to pharmacy numbers in each PhARIA, the most significant increases were observed for PhARIAs 2 (rural) and 5 (remote) of around 8% in each case, with a small decrease seen for PhARIA 1 (highly accessible) of 0.5%. However, these observations need to be tempered by the variable number of pharmacies for which PhARIA were unassigned in each year.

Impacts on stakeholders

Community pharmacies will be most directly affected by any changes to pharmacy remuneration and publicly funded community pharmacy programs. The specific parameters for pharmacy remuneration under the 7CPA were uniquely negotiated and agreed between Government and the Guild, as a representative of a majority of approved pharmacists, for the purposes of section 98BAA(1) of the Act.

Under the 7CPA, consumers will continue to be able to access medicines and pharmacy services. Consumers will be affected by changes to pharmacy remuneration in relation to potential increases to medicines priced below the PBS general patient co-payment where there is no pharmaceutical benefit paid by the Commonwealth. However, the reduction in the level of allowable discretionary fees permitted to be charged by pharmacists for the cost of medicines below the general patient co-payment goes some way to reduce this impact. As indicated above (Table 4), the indexation for pharmacy remuneration was below CPI for the second and third years of the 7CPA, and will be based on CPI for the fourth and fifth years of

[38] Data source: PBS online claims data maintained by the Department of Health and Aged Care and sourced from Services Australia. Data extracted 24 August 2022.

the Agreement. Therefore, the overall increase in pharmacy remuneration under the 7CPA would be broadly consistent with indexation in the long-term.

All pharmaceutical wholesalers will benefit from the introduction of a wholesale mark-up floor price for the supply of low-cost PBS medicines. The six wholesalers participating in the CSO Funding Pool arrangements will further benefit from the increase to the CSO Funding Pool (from $991 million over five years to $1.08 billion over five years) on commencement of the 7CPA.

Pharmaceutical manufacturers that supply medicines with Special Pricing Arrangements or with a Brand Price Premium may have been impacted by increased costs on commencement of the 7CPA.

Changes to Community Pharmacy Programs will impact pharmacy owners, pharmacists engaged in their delivery, and eligible members of the public. Continuation of the 6CPA pharmacy programs in their existing form from 1 July 2020 for the first year of the 7CPA has provided for implementation and transition activities for redesigned programs to be phased in from year two of the 7CPA. This approach is expected to have lessened impacts on providers and community pharmacy from program changes.

The 7CPA has introduced broader and more inclusive governance arrangements including ongoing formal representation from key stakeholders including Aboriginal and Torres Strait Islander and consumer representative organisations, in addition to the Guild and PSA. Whereas this will be of immediate benefit, in terms of formal representation and consultation, as opposed to stakeholders not having had a role in the governance of previous CPAs, this may bring a level of administrative burden for certain stakeholders in maintaining a regular increased level of engagement. However, with regular stakeholder engagements likely to occur more increasingly via videoconferencing means, this can be expected to present little burden to key stakeholder representative groups.

Regulatory burden of new and amended programs under 7CPA

An analysis of the potential regulatory burden on key stakeholders of changes brought about by the introduction of new and amended programs and services under the 7CPA is presented at ***Appendix 3***.

Regional Pharmacy Maintenance Allowance Program

As described above, from 1 January 2021, the basis for RPMA eligibility and payments was changed from the use of PhARIA categories to the Modified Monash Model (MMM) rural classification system. It is considered that these changes to the RPMA program will have caused minimal change in regulatory burden to eligible pharmacies. This is based on the regulatory impact for eligible pharmacists completing the registration process for both initial and renewal applications under the new arrangements not being material, as these processes do not differ to those under previous arrangements. In addition, any minimal time impost for eligible pharmacists in completing the online application or annual recertification is compensated by payment of the monthly RPMA allowance.

Closing the Gap (CTG) PBS Co-payment program

Under the 7CPA, the CTG PBS Co-payment program underwent changes from 1 July 2021 to expand the outreach of these services which provide affordable access to PBS medicines for Aboriginal and Torres Strait Islander people living with, or at risk of, chronic disease. One of these changes was to enable Aboriginal and Torres Strait Islander patients to be registered for the program regardless of their chronic disease status and where in Australia they live.

Whereas a minor additional compliance burden exists for providers involved with the new registration process, dispensing pharmacies are not involved in the registration process for patients. Therefore, it is considered that there is no change in existing regulatory burden on pharmacies for dispensing CTG prescriptions under the new arrangements introduced under the 7CPA.

Indigenous Dose Administration Aids (IDAA)

This program is a new community pharmacy program under the 7CPA, designed to assist Aboriginal and Torres Strait Islander patients in the community to better manage their medicines, with the objective of avoiding medication misadventure and improving medication adherence. The IDAA Program closely follows the existing DAA program but differs in that IDAA is an uncapped program and there is no charge to the patient in accessing an IDAA service.

The monitoring and compliance requirements for the IDAA program are identical to those of the existing DAA program and are therefore considered to have minimal regulatory impact. It is expected that for pharmacies with existing DAA services in place, there would be minimal burden in setting up facilities for the provision of an IDAA service.

Indigenous Health Services Pharmacy Support (IHSPS) Program

The IHSPS Program was created by merging the Quality Use of Medicines Maximised for Aboriginal & Torres Strait Islander People (QUMAX) and S100 Pharmacy Support Allowance programs, which continued from the 6CPA during the first year of the 7CPA (until 30 June 2021).

The IHSPS Program provides additional support services to Indigenous Health Services (IHS) and approved service providers to ensure better QUM health outcomes for Aboriginal and Torres Strait Islander people living in the community.

Based on the number of all eligible IHS service providers in 2021-22, the annual red tape impact for service providers is estimated as $27,515.24 per provider.

The true regulatory impact of this program will only be clear with passing time. For participating service providers, there are clear reporting and monitoring requirements which constitute a regulatory burden. These requirements are necessary to ensure that funds are being utilised in accordance with IHSPS Program requirements.

Which stakeholders have been consulted?

Stakeholder consultations on the development of the 7CPA

In line with a Government commitment to lead early and inclusive consultations to inform the 7CPA, the Department consulted with a range of national pharmacy, health and consumer organisations during development of the 7CPA. This included two stakeholder roundtable meetings hosted by the Department on 23 July 2019 and 14 November 2019.[39]

In total the Department held over 110 consultation and negotiation meetings, with national pharmacy, health and consumer organisations to inform the development of the 7CPA.

The Department also convened a number of meetings with agencies across government including the Department of Finance, Department of the Prime Minister and Cabinet, Treasury, Department of Veterans' Affairs and Services Australia, to discuss options and the approach taken in development of the 7CPA.

Significant features of the 7CPA arising from these consultations include:

- inclusion of the PSA as a co-signatory to the Agreement;
- more inclusive consultation arrangements bringing a higher level of stakeholder representation to operation of the agreement;
- improved patient access to medicines information, including increased transparency about discretionary charges applied by pharmacies;
- restructure and reform of the remuneration for wholesaling and distributing PBS medicines and the CSO Funding Pool arrangement for wholesalers;
- increased investment in Rural Pharmacy Maintenance Allowance to support greater consumer access to PBS medicines and pharmacy services in rural and remote locations; and
- improved access to medicines for Aboriginal and Torres Strait Islander peoples under pharmacy programs.

Stakeholder consultations for the 7CPA PIR

In informing this PIR the Department consulted with member organisations represented on both the CPCC and PSCC as the two main consultation fora under the 7CPA. To this end, the Department met individually with each of the organisations described below, during February 2022, to discuss their opinions and perspectives on a number of issues relevant to evaluating the effectiveness of the 7CPA in delivering on its intended objectives. Following these discussions, each organisation provided written responses to a number of specific questions relating to the operation of the 7CPA. The outcomes of these consultations are discussed further in detail below.

[39] www1.health.gov.au/internet/main/publishing.nsf/Content/7cpa-communique-23July2019 and www1.health.gov.au/internet/main/publishing.nsf/Content/7cpa-communique-14November2019

In concert with this process, the Department also consulted with internal program areas within the Department responsible for the management, administration and reporting of programs and services delivered under the 7CPA. Observations arising from these discussions have informed the analysis of benefits delivered by the 7CPA, which are discussed in the following section of this report.

The Pharmacy Guild of Australia (Guild)

The Guild is the national peak body representing the business and professional interests of community pharmacy in Australia. While primarily seeking to serve the interests of its members, the Guild also seeks to support the role of community pharmacy in delivering quality health outcomes for all Australians.

The Guild operates as a registered national employers' organisation with membership limited to owners of community pharmacies, representing 75% – 80% of all pharmacy owners. This amounts to around 4000 community pharmacies employing some 20,000 registered pharmacists.

The Guild is a signatory to the 7CPA, and has been signatory to all previous Community Pharmacy Agreements with regards to formalising an agreement on the remuneration of approved pharmacists for the supply of PBS medicines, being recognised as an *"organisation that represents a majority of approved pharmacists"* for the purposes of section 98BAA(1) of the Act.

Pharmaceutical Society of Australia (PSA)

The PSA is the peak national body representing the interests of the pharmacy profession in Australia and includes pharmacists working across all sectors and locations nationally. PSA is the custodian of the pharmacist professional practice standards and guidelines to ensure quality and integrity in the practice of pharmacy and supports pharmacists to develop into providers of high-quality, ethical professional services to their community. The PSA has approximately 18,000 members nationally and is invested in optimising the professional role of the pharmacist to improve healthcare in Australia.

As a first-time co-signatory to the 7CPA, the PSA is recognised as custodian of the Code of Ethics, National Competency Standards Framework for Pharmacists, Professional Practice Standards and Practice Guidelines governing the professional practice of pharmacists, and in providing support to the design, implementation and evaluation of Community Pharmacy Programs under the 7CPA.

Consumers Health Forum of Australia (CHF)

CHF is the peak national body representing the interests of healthcare consumers in Australia and works to support the provision of safe, quality and timely healthcare for all Australians. CHF advocates for all healthcare consumers and actively supports consumer participation in health policy through its various consumer-based research activities.

CHF's members include peak health consumer organisations from different states, organisations or networks dedicated to specific health conditions as well as organisations involved in other healthcare consumer affairs.

National Aboriginal Community Controlled Health Organisation (NACCHO)

NACCHO is the national peak body for Aboriginal and Torres Strait Islander peoples' health in Australia. The organisation represents the 144 Aboriginal Community Controlled Health Organisations (ACCHOs) across the country on Aboriginal and Torres Strait Islander health and wellbeing issues and is also the third largest employer of Aboriginal and Torres Strait Islander peoples with over 50% staff in ACCHOs being of Aboriginal and Torres Strait Islander origin.

The organisation advocates for solutions that contribute to improved Quality of Life and health outcomes for Aboriginal and Torres Strait Islander peoples and provides advice and guidance to Government on policy and budget matters pertaining to Aboriginal and Torres Strait Islander health.

NACCHO's primary health care network involves more than 550 sites nationally providing 3.1 million episodes of care per year for almost 410,000 people across Australia, including about one million episodes of care in remote regions.

Outcome of Stakeholder consultations

An overview summary of the views of the Guild, PSA, CHF and NACCHO relating to key aspects of the implementation and operation of the 7CPA is presented in Table 11 below.

Table 11. Key stakeholders' views on consultation themes for the 7CPA PIR.

Consultation theme	Guild	PSA	CHF	NACCHO
7CPA measures were appropriate to:				
• Ensure access to safe and affordable medicines	+++	+++	+++	+
• Ensure quality use of medicines services	+++	±	+	±
• Monitor health outcomes for patients	+++	–	–	–
The consultation committees work effectively to support the delivery of 7CPA implementation activities	+++	–	–	+
7CPA implementation activities:				
• Stakeholder support for activities was effective	+++	–	–	–
• Positive impact on consumers/patients	+++	+	–	–
• Implementation activities were successful	+++	+	+	+
Increased government investment has improved pharmacy services under 7CPA	+++	+	–	±
7CPA services have been beneficial for:				
• Patients	+++	±	±	–
• Indigenous populations	+++	±	±	–
• Community pharmacy sector	+++	+++	+++	+++
Engagement and collaboration of stakeholder representatives	+++	–	±	–

Key: Agree completely (+++), Somewhat agree (+), Do not agree (–), Unsure (±)

A synopsis of written consultation responses received from each of the above stakeholder organisations is presented below.

How does implementation of the 7CPA provide appropriate measures to improve access, safety, and quality use of PBS subsidised medicines?

The Guild, PSA, CHF and NACCHO each considered that 7CPA services ensured access to safe and affordable medicines to all Australians via a national network of qualified community pharmacists, while also providing business certainty to pharmacy owners for the life of the agreement. However, all but the Guild felt that it was not possible to determine the effectiveness of 7CPA services due to a lack of available data.

The Guild also noted the importance of 7CPA services in continuing to ensure timely distribution of medicines to consumers by maintaining CSO arrangements for full-line pharmaceutical wholesalers, recognising the additional requirements in managing, dispensing and real time monitoring of Controlled Drugs by increasing the Dangerous Drugs Fee, and acknowledged the continued commitment to support pharmacy vaccination programmes.

CHF supported a similar view, noting that the 7CPA supports access to PBS medicines through a well-resourced and qualified network of community pharmacies which is valued by consumers. The PSA noted that Government's five-year investment through the 7CPA provides certainty to community pharmacy owners and their businesses, and in enabling the supply of essential PBS medicines to local communities.

The PSA, however, felt that the current structure and implementation of the 7CPA lacked the measures and data collection processes to support an understanding of how the 7CPA supports the safe and quality use of medicines. NACCHO similarly was of the view that the scarcity and quality of publicly available data on medicines and associated data for Aboriginal and Torres Strait Islander populations make it difficult to comment authoritatively on the 7CPA's impact on access, safety and quality use of medicines.

The PSA noted that, aside from the 7CPA encouraging high-volume dispensing of PBS medicines and driving quantity over quality of service, the operation of community pharmacy programs under the 7CPA (noted as essentially unchanged from the previous CPA) also encourages a similar quantity over quality approach. PSA argued that limited or lack of data to allow meaningful evaluation of these program results in patients, pharmacy, government and taxpayers not being able to quantify the value of the pharmacist's role in primary care. CHF felt that the 7CPA is a very prescriptive agreement that does not encourage innovation and reduces the capacity for flexible approaches to meet new challenges. That said, CHF did note the 7CPA's provision[40] allowing Government to undertake pharmacy and medicines initiatives outside of the 7CPA as a positive.

[40] Clause 16.3.1 of the 7CPA states: "Nothing in this Agreement, or any other document connected with this Agreement, limits the ability of the Australian Government to announce or implement policy reforms that may impact the community pharmacy sector or the pharmacy profession."

NACCHO suggested there should be more emphasis on the impact on consumers, particularly those with historically poorer access to PBS medicines and associated services, including Aboriginal and Torres Strait Islander peoples. NACCHO further proposed that future CPA arrangements should have greater consideration of consumer needs, including alternate ownership arrangements that improve ownership of pharmacies by Aboriginal Community Controlled Health Organisations (ACCHO).

PSA recommended that other funding mechanisms and frameworks be explored for funding services supported under the 7CPA. This was echoed by CHF reiterating its argument, previously made in its submission to the Pharmacy Review, that if CPAs are to be retained the first step for reform should be splitting the current agreement into two, with one part dealing with remuneration and dispensing issues and the second covering pharmacy programs and associated quality use medicines issues.

The Guild further noted the development of Key Performance Measures (KPM) for the 7CPA aimed at enabling stakeholders to assess the impacts of the 7CPA and whether its objectives have been effectively and efficiently achieved. CHF also welcomed the development of KPM's for the 7CPA but felt that this activity was constrained by there being no funding for new data collection activities under the 7CPA.

How well have the 7CPA Consultation Committees supported the delivery of 7CPA implementation activities which commenced on 1 July 2020?

Almost all stakeholders believed that both Consultation Committees, while an improvement on governance structures that were in place with previous agreements, were failing to achieve the full intended purpose of these committees.

The Guild recognised that the 7CPA Consultation Committees (CPCC and PSCC) provide a mechanism for identifying actual or potential issues for resolution, noting in particular that the committees had together developed an implementation plan[41] and a Key Performance Measure (KPM) framework for the 7CPA.

The PSA voiced concern that the PSCC, on which it is a representative, had fallen short of its expectations in terms of meeting its intended functions. Noting that the PSCC's terms of reference[42] articulate responsibilities incorporating the provision of feedback and advice from stakeholders, the PSA felt that in meetings to date there had been minimal opportunity for robust discussion of issues.

The PSA also noted with concern that ad hoc meetings with key stakeholders had occurred routinely outside of PSCC meetings, limiting the range of viewpoints and well-rounded engagement. The PSA further noted that the CPPC had not referred matters to the PSCC to facilitate more inclusive consultation with the broader representation of this forum. However,

[41] www.pbs.gov.au/info/general/seventh-community-pharmacy-agreement-7cpa-consultation-com
[42] www.pbs.gov.au/general/7cpa/Pharmacy-Stakeholder-Consultation-Committee-Terms-of-Reference.pdf

the PSA also noted that there was provision for review of arrangements for the CPCC and PSCC under the terms of the 7CPA.[43]

CHF felt that, although disappointing, the PSCC had been better than previous stakeholder forums under the 6CPA. CHF specifically noted collaboration on certain activities arising from discussion at the PSCC, including in relation to the development of information on PBS medicines price transparency for consumers.

CHF echoed PSA's concerns regarding the PSCC's limited visibility of discussion in the CPCC, particularly in relation to issues having significant impact on implementation, and from which there continued an impression of key decisions being taken between the Department and Guild only.

NACCHO supported the intent of a more accountable and inclusive consultation process for the 7CPA, through the formation of the PSCC. However, NACCHO too felt that the reforms and actions resulting from this forum have not substantially reflected meaningful consultation, due in part to limited engagement from participants in addressing stakeholder concerns.

To what extent have 7CPA implementation activities been delivered? How well and to what extent have 7CPA key stakeholders supported the implementation of 7CPA activities?

Stakeholders considered that 7CPA implementation activities were hampered by a lack of adequate stakeholder engagement and lack of communication on progress.

The Guild noted that changes to pharmacy remuneration under the 7CPA were implemented seamlessly, in comparison to the changes made on commencement of the 6CPA. This was explained as being due to the remuneration structure under 7CPA being consistent with that of the 6CPA, which had brought significant changes to pharmacy remuneration to the (previous) 5CPA.

In particular, the Guild noted that changes to the CTG PBS Co-payment program had been problematic and have relied on peak bodies working together to address communication of changes, patient access and registration issues. NACCHO also pointed to specific difficulties in implementation of Indigenous Community Pharmacy Programs (IDAA, IHSPS and CTG PBS reforms), and noted its concern over there being no substantive monitoring and evaluation activities under the structure of the 7CPA.

The Guild and NACCHO noted the development of Key Performance Measures (KPM) under the 7CPA. However, NACCHO felt that the KPM are inadequate in scope and do not capture health outcomes.

The PSA noted that limited information had been made available to the public and key stakeholders regarding implementation of 7CPA activities, including through the PSCC. PSA specifically pointed to a lack of information regarding progress on assessment of Community Pharmacy Programs and establishment of new pharmacy programs under the 7CPA.

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[43] Clause 16.4 of the 7CPA.

The Guild further noted that the 7CPA was implemented during the COVID-19 pandemic, when priorities for community pharmacy have been dispensing and responding to COVID-19 issues, with other professional activities being secondary and subject to available pharmacy resourcing.

CHF felt that progress on implementation activities under the 7CPA had in general been hampered by a lack of engagement from relevant stakeholders.

To what extent have benefits for patients been achieved in relation to transparency of costs and Consumer Medicines Information as part of the 7CPA?

All stakeholders, with the exception of the Guild, indicated that while resources had been developed, they did little to address consumer concerns.

The Guild noted that it had developed resources (an in-pharmacy poster and FAQ) to improve transparency of costs for patients, making these publicly available from February 2022.[44]

PSA, while noting that these resources were developed in collaboration with key stakeholders, felt that they would do little to facilitate significant change. CHF felt that whilst meeting the letter of requirements under the 7CPA, these resources fail to inform consumers of the costs of their medicines prior to being dispensed. NACCHO similarly felt the resources do not address genuine concerns of consumers about costs and quality of information being provided by pharmacies.

CHF further felt that little progress had been made in relation to the provision of Consumer Medicines Information (CMI) to consumers, as discussions had been constrained by the wording of the 7CPA. NACCHO further questioned the appropriateness of CMI for certain patient groups including Aboriginal and Torres Strait Islander peoples, suggesting there needs to be wider consideration of health literacy issues and increasing patient access to reputable information sources regarding medicines in varying formats.

How has the increase in government investment provided improvements to Community Pharmacy Programs and services delivery under the 7CPA?

Most stakeholders felt that despite increased investment, there was no clear evidence of the impact of increased investment due to a lack of appropriate evaluation measures.

The Guild noted its concern that increased pharmacy programs funding under the 7CPA may be insufficient to meet patient demand. The Guild specifically noted the number of services administered in HMR, RMMR, MedsCheck, Diabetes MedsCheck and DAA programs in the last year of 6CPA (2019-20) was $15.18 million and was $16.54 million in the first year of the

[44] www.findapharmacy.com.au/pbs-pricing

7CPA (2020-21), representing an increase of $1.4 million (8.9%) in services provided to patients.

PSA noted that the lack of evaluation built into the design of community pharmacy programs changes under the 7CPA means that there is no way of accurately determining the impacts of increased spending. PSA further noted specific impacts in relation to implementation of changes to the RPMA program, implementation of the IDAA Program, IHSPS Program and CTG PBS co-payment reforms.

CHF felt that there had been no real changes to continuing community pharmacy programs, and again suggested that pharmacy programs should be separated out, funded, and administered separately from an agreement focusing on pharmacy remuneration.

NACCHO observed that increased funding had not been evident for all pharmacy programs, with varied spending and uptake across different program streams. NACCHO noted that data was unavailable for it to comment on IHSPS or CTG spending but that the IDAA program appeared to be over-budget with performance indicators unavailable to assess value.

How well has government expenditure on programs and services translated into a net benefit for community pharmacies and Australians, including Aboriginal and Torres Strait Islander people?

All stakeholders acknowledged improved access to medicines for all patients and in particular Indigenous patients due to better targeting of program services and more inclusive eligibility criteria. Nearly all stakeholders concurred that due to the paucity of appropriate evaluation data, it was not possible to ascertain the real impact of patient benefits.

The Guild stated that benefits to patients were evident from:

- Increased services compared to the last year of the 6CPA suggesting additional demand has been met, including from Aboriginal and Torres Strait Islander people.
- CTG reforms having improved eligibility criteria to be more inclusive for Indigenous people.
- The IDAA program ensuring access by Aboriginal and Torres Strait Islander patients to improve patient medicine adherence.

The Guild also noted that pharmacy income generated from dispensing and related services under the 7CPA had supported the community pharmacy sector in responding to the COVID-19 pandemic. In addition to community pharmacy's role in supporting the COVID-19 vaccination program and the supply of concessional Rapid Antigen Tests, the Guild noted Government's implementation of complimentary arrangements, such as the Home Medicines Service, supporting the delivery of PBS medicines to people in isolation.

CHF similarly noted the impacts on community pharmacy from the COVID-19 pandemic during implementation of the 7CPA. CHF also noted the benefits to community pharmacy from guaranteed income and certainty brought by the 7CPA, and benefits to the community from a viable and sustainable national network of community pharmacies providing access to

PBS medicines. However, CHF further noted difficulty in quantifying the benefits and impacts of the 7CPA due to limitations in available data for analysis.

NACCHO, while recognising the 7CPA's support for the viability of the pharmacy sector, noted the importance of patient outcomes, and that benefits to patients were less easy to demonstrate than the flow of funding to community pharmacy. NACCHO specifically noted this difficulty for Aboriginal and Torres Strait Islander people for whom minimal specific data are captured to measure this net benefit.

PSA echoed its earlier comments (in relation to the previous question, above) regarding the lack of evaluation built into the design of community pharmacy programs changes under the 7CPA, and impacts in relation to implementation of changes to the RPMA program, implementation of the IDAA and IHSPS programs and CTG PBS co-payment reforms.

How well has the community pharmacy sector as a whole benefitted from the delivery of programs and services under the 7CPA?

All stakeholders agreed that the community pharmacy sector has benefitted most by ensuring continuity of 7CPA services.

The Guild noted that the 7CPA recognises community pharmacy as an integral part of the healthcare system through its role in supporting the PBS, and that predictable remuneration for community pharmacy is required to support its viability.

The Guild further noted that while dispensing remains the largest professional service, the professional programs and services components of the 7CPA provide vital complementary services for patients and from a business perspective, assist in enabling community pharmacies to employ pharmacists, interns, technicians, and pharmacy assistants to not only service the Australian public with PBS and 7CPA services, but with other health services such as vaccinations.

The Guild and PSA both agreed that the 7CPA has delivered a level of certainty to the sector, maintaining the viability of the community pharmacy network. The Guild noted this provides the sector with a stable business environment for a 5-year period which assists in the financial and human resource components of managing the business. The Guild further noted that in the absence of the 7CPA, the sector would be relying on annual reviews for PBS remuneration arrangements which would make business operations much less stable and more difficult to negotiate.

The PSA however, noted that Community Pharmacy Programs under the 7CPA had remained largely unchanged from the 6CPA with equivalent funding having been maintained in the first two years of the 7CPA making it difficult to quantify any benefit.

The PSA further noted that the new or enhanced programs that had commenced since the start of the 7CPA do not incorporate mechanisms for robust evaluation.

On this basis, PSA questioned whether the 7CPA remains the most appropriate approach to supporting access to PBS medicines, programs, and related services in the community. Noting that professional pharmacy programs are no longer delivered exclusively through

community pharmacy, the PSA contested that it is no longer appropriate for these programs to be contained within a CPA.

CHF noted that while community pharmacy had clearly benefitted from the 7CPA, it was not clear how others involved in providing pharmacy services, such as consultant pharmacists delivering HMRs and RMMRs, may have benefited.

NACCHO felt that the 7CPA had disproportionality benefited community pharmacy, compared to consumers.

To what extent have pharmacy sector representatives effectively engaged and consulted in consultations and implementation of the 7CPA?

Most stakeholders highlighted a lack of transparency as the main setback for effective engagement despite a general improvement in involvement of increased representation of varied stakeholders.

The Guild recognised that CPAs have continued to operate as arrangements agreed between Government and the community pharmacy sector on pharmacist remuneration for dispensing PBS medicines and related programs and services through community pharmacies.

In addition to its participation as a standing member of the 7CPA CPCC and PSCC, the Guild acknowledged its ongoing participation in ad hoc meetings with the Department on matters relating to the 7CPA.

The Guild further recognised that it has also continued to actively engage with other stakeholders in relation to the needs of patients and the broader sustainability of the supply chain, including: PSA, Medicines Australia, Generic and Biosimilars Association (GBMA), NPSA, RACGP, NACCHO, Rural Pharmacy Alliance, TGA, Pharmaceutical Benefits Advisory Committee (PBAC), Australian Patients Association, CHF, Australian Digital Health Agency (ADHA), Medicines Software Industry Association (MSIA) and Australian Commission for Safety and Quality in Healthcare.

PSA again noted its concerns regarding 7CPA governance arrangements post 7CPA execution, notably in relation to transparency surrounding 7CPA implementation activities and the absence of data or mechanisms for robust evaluation and outcomes analysis.

CHF noted having limited contact with the pharmacy sector other than through the 7CPA PSCC and related activities.

NACCHO noted that whereas consultation has featured during the 7CPA, little information is available as to how this has addressed stakeholder needs. In relation to Indigenous pharmacy programs, NACCHO specifically felt that there had been deliberate influence outside of the consultation process, leading to less effective programs appropriate to the needs of Aboriginal and Torres Strait Islander people.

Has the 7CPA delivered a net benefit to date?

As previously stated, the fundamental objective of the CPAs is to ensure equitable and affordable access to PBS medicines for all Australians through Australia's network of community pharmacies.

This PIR has considered the objectives of the 7CPA, its impacts, its effectiveness and efficiency in meeting its objectives. In considering whether the 7CPA has delivered a net benefit, impacts were compared to 6CPA. In particular, the 7CPA aimed to improve on the 6CPA in terms of:

- providing increased access to community pharmacy programs;
- providing better support for regional, rural and remote pharmacies; and
- improving access to medicines for Aboriginal and Torres Strait Islander people.

This has included an examination of PBS expenditure, dispensing remuneration to community pharmacists, community pharmacy programs and related services, and other fees and allowances paid to community pharmacists.

Additional key funding arrangements under the 7CPA, such as CSO funded activities and NDSS product distribution arrangements, have also been considered.

Governance arrangements under the 7CPA, centred around operation of the CPCC and PSCC, have also been examined with stakeholders internal and external to the Department to determine whether these consultation arrangements are meeting agreed objectives and providing expected outcomes for stakeholders.

Access to medicines

As outlined above, there has been a real increase in PBS dispensing volumes through community pharmacies following commencement of the 7CPA (0.8%), compared to the population increase in the same period (0.13%). Further, while there has been little difference in the spread of pharmacies (Table 9), there was a significant increase in PBS prescription volume observed in rural and remote pharmacies following commencement of the 7CPA (Table 10). Therefore, the 7CPA has ensured continued access to PBS medicines via the network of community pharmacies throughout Australia.

The 7CPA has seen significant increased investment in the pharmaceutical wholesaling space both in terms of an increased investment in the CSO Funding pool ($991m under 6CPA vs $1.083m under 7CPA) and in the introduction of a wholesale floor price of 41 cents for medicines priced at or below $5.55 (AEMP).[45] It is noted that during 2021, CSO wholesalers had continued to ensure timely delivery of PBS medicines amidst distribution centre closures due to COVID-19 outbreaks, and that increased Government investment under the 7CPA will have supported these activities.

Amendments to the CSO Deeds on commencement of the 7CPA introduced the ability for the Department to issue written directions allowing CSO distributors to restrict supply of stock

[45] Approved Ex-Manufacturer Price (AEMP), as agreed between government and manufacturer, is the price charged by the manufacturer for medicines listed on the Pharmaceutical Benefits Scheme.

under *force majeure* events. This follows from action taken in early 2020 in response to medicines shortages resulting from panic buying of certain medicines by pharmacies and consumers during the early stages of the COVID-19 pandemic. In the lead up to the 1 October 2020 implementation of increased AEMP for low-cost PBS medicines, as an outcome of the Government's Strategic Agreements with Medicines Australia and the Generic and Biosimilar Medicines Association, the Department issued notices to CSO distributors to assist with the reduction of stockpiling by pharmacies.

Community Pharmacy Programs

Following commencement of the 7CPA, there has been an increase in the number of services provided through all Community Pharmacy Programs (Table 5), reflecting the increased investment in Community Pharmacy Programs in the 7CPA compared to that of the 6CPA.

In terms of program evaluation, the lack of appropriate data collection to inform on effectiveness of increased 7CPA services is a drawback that needs to be rectified through further stakeholder consultation. While there has been improvement to timeliness and granularity of data reporting under 7CPA compared to the previous agreements, only minimal health outcomes data continue to be collected.

The 7CPA is continuing to support improvements to programs data collection that were implemented under the 6CPA with the introduction of the Pharmacy Programs Administrator (PPA) from February 2019, as the agency responsible for administering, processing and paying claims for Community Pharmacy Programs. Under these arrangements, community pharmacy programs data has continued to be published via the Department's website[46] since July 2020.

As noted by stakeholders, the amount and type of data collected through Pharmacy Programs in particular makes it difficult to draw conclusions on health outcomes. Any increase in data collection also needs to be balanced with the increased burden this would incur on pharmacists and patients.

Support for regional, rural and remote pharmacies

Reforms to the RPMA program on 1 January 2021 have resulted in an additional 241 pharmacies in rural and remote communities receiving financial support to ensure ongoing access to PBS medicines for people living in rural and remote areas.

Access to medicines for First Nations people

Changes to Community Pharmacy Programs for First Nations peoples has seen greater accessibility of medicines, with 70,000 new patients registered for the CTG PBS Co-Payment program in the first 12 months following program changes (Table 7). In addition, the

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[46] www.health.gov.au/resources/collections/pharmacy-programs-data

introduction of the IDAA and IHSPS programs in July 2021 have seen strong uptake, although it is too early to draw conclusions on the impact of these programs.

Improvements in stakeholder engagement and consultation

The introduction of the PSCC under the 7CPA has seen improvements in encouraging ongoing participation in program discussions from its standing members (Guild, PSA, CHF and NACCHO).

It should be noted that the Department has consulted widely on program reform beyond the 7CPA's two formal consultation committees, making genuine efforts to build consultation into program development so that the final product appropriately reflects stakeholder interests and input. For example, in developing the IDAA program under the 7CPA, the Department consulted not just with PSCC members (Guild, NACCHO and PSA) but also with a range of stakeholders relevant to Indigenous matters.

The PSCC continues to provide benefit in terms of formalising consultations on 7CPA related matters with stakeholders in addition to the Guild. Notably, there was more extensive engagement with stakeholders outside of the PSCC in the development of the new Indigenous Quality Use of Medicines and IDAA programs.

However, discussions have been restricted in some instances, with stakeholders responsible for implementation of certain programs having been excluded from key decision making. Concerns have been raised about undue influence exerted by some stakeholder organisations to potentially aid their particular pecuniary interests. Another concern was that program reforms planning and discussions did not always include appropriate representation leading to program changes that were not tailored to that patient or consumer population needs.

Professional Practice Standards and Guidelines

As a co-signatory to the 7CPA, PSA has a role under Part II of the 7CPA as custodian of the Code of Ethics, National Competency Standards Framework for Pharmacists, Professional Practice Standards, and Practice Guidelines governing the professional practice of pharmacists in Australia. In terms of continuity of activities between the 6CPA and 7CPA, it should be noted the PSA had been contracted under the 6CPA and previous CPAs to review and update the relevant Standards and Guidelines. The PSA has similarly been engaged under the 7CPA to continue to maintain the Professional Practice Standards and relevant clinical guidelines.

National Diabetes Service Scheme distribution arrangements under the 7CPA

The 7CPA continues to support funding arrangements previously in place under the 6CPA, for the distribution of NDSS products through community pharmacies.

How has the 7CPA been implemented and evaluated?

Implementation of the 7CPA

Implementation of the 7CPA from 1 July 2020 has continued activities previously supported under the 6CPA in respect of funding of community pharmacy medication management programs and related services delivered through community pharmacies.

Key changes and activities implemented under the 7CPA to date broadly relate to:

- *Remuneration* – including revised pharmacy fees, wholesaler mark-up structure and risk share arrangements through the RAM;
- *Community Pharmacy Programs* – including continuation and reprioritisation of existing (6CPA) programs and introduction of new Indigenous pharmacy programs;
- *Revised governance arrangements* – comprising formation of two new consultation committees; and
- *Other activities and arrangements* – including maintenance of Code of Ethics, professional standards and guidelines for pharmacists, transparency of medicines pricing for patients.

Pharmacy Remuneration changes – *1 July 2020*

The following changes were implemented from 1 July 2020, in respect of pharmacy and wholesaler remuneration on commencement of the 7CPA:

- *Increase to pharmacy dispensing remuneration* – through increases to the Administration Handling and Infrastructure (AHI) Fee, dispensing fee (for ready-prepared and extemporaneously-prepared pharmaceutical benefits) and Dangerous Drug Fee. These changes were implemented in legislation via the Commonwealth Price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020,[47] as made by the PBRT on 26 June 2020.
- *Increase to the Safety Net Recording fee* – implemented in legislation via the National Health (Pharmaceutical Benefits) (Subsection 84C(7) Price) Amendment (Seventh Community Pharmacy Agreement) Determination 2020,[48] as made on 26 June 2020.
- *Decrease in the Additional Patient Charge* – applicable to medicines priced below the maximum PBS Patient co-payment. This change was implemented in legislation via the National Health (Pharmaceutical Benefits) Amendment (Seventh Community Pharmacy Agreement) Regulations 2020,[49] as made by the Governor-General on 9 July 2020.

[47] www.legislation.gov.au/Details/F2020L00806
[48] www.legislation.gov.au/Details/F2020L00820
[49] www.legislation.gov.au/Details/F2020L00898

Wholesale mark-up changes – *1 January 2021*

From 1 January 2021, changes to the wholesale mark-up component of the Commonwealth price were made, introducing a floor price of 41 cents for PBS medicines with an AEMP of $5.50 or below. This change was made via an amendment to the *Commonwealth Price (Pharmaceutical benefits supplied by approved pharmacists) Determination 2020,* made by the PBRT on 30 November 2021.

Remuneration Adjustment Mechanism (RAM) – *1 July in years 2 ,3, 4 and 5 of 7CPA*

Clause 3 and Appendix B of the 7CPA provide details of the operation of the volume-based RAM as a mechanism for adjusting the Commonwealth price paid to approved pharmacists for the dispensing of Pharmaceutical Benefits in respect of greater or lower than estimated actual PBS and RPBS subsidised script volumes for any given assessment period during the term of the 7CPA.

For the first and second assessment periods (1 July – 31 December 2020 and 1 January – 31 December 2021) the Department performed the calculations as set out in Clause 3 and Appendix B of the 7CPA and determined that no adjustment was required to the Commonwealth price in the second and third years of the 7CPA.

As indicated in Table 12 below, for both the First and Second Assessment Periods, the number of Actual PBS and RPBS Subsidised Prescriptions was within five (5.0) per cent above the number of Estimated Subsidised Prescriptions for each respective Assessment Period.

Table 12. Actual vs estimated* PBS and RPBS prescription volumes for First and Second Assessment Periods of 7CPA

Assessment Period	1 Jul – 31 Dec 2020	1 Jan – 31 Dec 2021
Estimated Prescriptions*	109,521,070	207,523,772
Actual Prescriptions	113,238,530	215,268,750
Variation (actual vs estimate)	***+3.39%***	***+3.73%***

** estimates of PBS and RPBS subsidised prescription volumes are as agreed under Appendix B of the 7CPA.*

Annual indexation of Pharmacy Remuneration – *1 July in years 2 ,3, 4 and 5 of 7CPA*

In keeping with annual indexation of Pharmacy Remuneration, as per clause 13 of the 7CPA, increases to the AHI Fee, Dispensing Fee for Ready-prepared Pharmaceutical Benefits and Extemporaneously-prepared Pharmaceutical Benefits, Dangerous Drug Fee and Safety Net Recording Fee were implemented from 1 July 2021, and subsequently from 1 July 2022, through amendments to the respective legislative instruments described above. As set out in Table 4, these fees were indexed by 0.5%, below the CPI for the previous quarter.

Annual increases to pharmacy remuneration will similarly be made from 1 July 2023 and 1 July 2024, and will be based on CPI.

Community Pharmacy Programs – changes to existing programs

Dose Administration Aids (DAA) Program

While continuing from the 6CPA, the DAA program was expanded from 4 January 2021 to increase the base cap from 30 to 60 services per week up to a maximum of 200 services per week. The number of services delivered increased by 1.5% in the first 18 months of the 7CPA compared to the last 18 months of the 6CPA (Table 5).

Rural Pharmacy Maintenance Allowance (RPMA) Program

Changes to the RPMA under the 7CPA, to increase investment in regional, rural and remote areas, have included:

- an increased funding allocation of $20 million in the first year of the 7CPA and $21 million in following years, compared to $16.4 million in the last year of the 6CPA;
- from 1 January 2021, a change from the PhARIA rural classification system to the MMM of rural classification.

As of 30 June 2021, there were 1029 pharmacies participating in the RPMA Program. This was an increase of over 200 pharmacies since the new allowance arrangements commenced on 1 January 2021 in areas ranging from large rural towns (MMM3) to very remote communities (MMM7).

Community Pharmacy Programs – Indigenous pharmacy programs – 1 July 2021

The following changes were implemented from 1 July 2021, to provide improved access to medicines for Aboriginal and Torres Strait Islander people:

Closing the Gap (CTG) PBS Co-payment reforms

These reforms have enabled Aboriginal and Torres Strait Islander patients to utilise CTG arrangements wherever they live and whatever their chronic disease status.

From 12 July to 30 September 2021, the Department, together with Services Australia, implemented a grace period to prevent CTG annotated prescriptions being rejected at the time of dispensing for Aboriginal and Torres Strait Islander patients not yet registered via the centralised registration system established for the program.

A communications strategy was developed to ensure timely messaging of the impacts of the reforms and was tailored for target audiences, including Aboriginal and Torres Strait Islander people, PBS prescribers and Aboriginal Health Practitioners, and pharmacies. An additional 70,000 patients were registered for the CTG PBS Co-payment program and a 15% increase in the number of prescriptions dispensed under the program was seen for the 12 months following the 1 July 2021 program changes (Table 7).

Indigenous Dose Administration Aids (IDAA) program,

The IDAA program was introduced as a new uncapped program with no patient contribution, providing culturally appropriate services and medication adherence to Aboriginal and Torres Strait Islander patients.

In the first month of operation of the IDAA program there were 1,727 registered service providers, over 720 claims and more than 41,000 services provided. The total amount paid for services was over $478,000.

Indigenous Health Services Pharmacy Support (IHSPS) program

Introduction of the IHSPS program in July 2021 replaced the former *QUMAX* and *S100 Pharmacy Support Allowance* programs which had continued from the 6CPA during the first year of the 7CPA.

The IHSPS program is aimed at supporting quality use of medicines (QUM) services and improved QUM and health outcomes for Aboriginal and Torres Strait Islander patients, by providing funding directly to eligible Indigenous Health Services for the purchase of a range of QUM Support activities.

The IHSPS Program Rules and funding model were agreed with the Guild, NACCHO and PSA following extensive consultation.

In the first six months of operation, the IHSPS provided 225 services with $1.96 million in funding for QUM services for First Nations people (Table 6).

Electronic Prescription Fee arrangements

Clause 9.4.1 of the 7CPA provides that after the first year of the 7CPA the Department will establish direct funding arrangements with prescription exchange services (PES) to facilitate pharmacists' receipt of electronic prescriptions and electronic copies of paper prescriptions:

- Prior to 1 July 2021 the Electronic Prescription Fee (EPF) had continued, as under the 6CPA, to be paid as a 15 cent incentive payment to pharmacists for each eligible prescription downloaded from a PES, for which the pharmacist is directly charged a 15 cent fee by the PES.
- Having commenced discussions with PES providers prior to 1 July 2021, the Department continues to investigate funding options and mechanisms for direct payment of the EPF to PES providers.
- The current EPF of 15 cents will be maintained until an operational direct payment model is in place.

The first year of the 7CPA saw a 10.6% increase in EPF compared to the final year of the 6CPA.

Revised consultation arrangements

The CPCC and PSCC were each established following commencement of the 7CPA as its primary consultation mechanisms:

- Terms of Reference for the CPCC were agreed between Government and the Guild, under Appendix C of the 7CPA.
- During the first six months of the 7CPA, the Department consulted with the Guild, PSA, CHF and NACCHO on Terms of Reference for the PSCC. These were endorsed by the Minister for Health, prior to the PSCC's first meeting in October 2020.

- Both committees meet biannually. To date, the CPCC and PSCC have each met four times, on 30 October 2020; 1 April 2021; 11 November 2021; and 15 June 2022.
- Communiques detailing key discussions and outcomes of each meeting have been published on the department's website.[50]

Code of Ethics, Professional Standards and Guidelines

Clause 14 of the 7CPA recognises the PSA's role as the custodian of the Code of Ethics, National Competency Standards Framework for Pharmacists, Professional Practice Standards, and Practice Guidelines governing the professional practice of pharmacists in Australia.

In April 2022, the Department engaged the PSA to continue to maintain the Professional Practice Standards and relevant clinical guidelines. This work will include review of standards and guidelines in the context of continuing community pharmacy programs and standards and guidelines requiring development or review in the context of new community pharmacy programs. This work is expected to be completed by 30 June 2023.

Transparency of medicines pricing for patients

Clause 4.3.2 of the 7CPA committed the Guild to working with the Department during the first year of the 7CPA to develop arrangements and processes for community pharmacists to inform consumers about the price of their PBS medicines prior to dispensing.

Following initial discussions at the PSCC's first meeting in October 2020, the Guild submitted draft resources to the Department for consideration. These were provided to PSCC representatives for further review and subsequent discussion at the PSCC's second meeting in April 2021.

On 30 June 2021, following focus group testing facilitated by CHF and further comment from PSA, CHF and NACCHO, the Guild provided revised resources to the Department.

Following the endorsement of PSCC representatives, the Guild provided the Department with an implementation plan and communication plan for finalisation and publication of its resources for pharmacists via its "Find a Pharmacy" website,[51] to coincide with PBS co-payment changes from 1 January 2022.

Evaluation

The 7CPA includes provision for review and assessment of activities supported under the Agreement.

Key Performance Measures (KPM) for the 7CPA

KPM for the 7CPA were developed over the first 18 months of the 7CPA in collaboration between the Department, Guild, PSA, CHF and NACCHO.

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[50] www.pbs.gov.au/info/general/seventh-community-pharmacy-agreement-7cpa-consultation-com
[51] www.findapharmacy.com.au/pbs-pricing

As no funds were made available under the 7CPA for monitoring and evaluation, the KPM have been confined to measures that stem from existing processes, available data and resources, with no additional costs to Government:

- The KPM and associated policy principles were approved by the Minister for Heath in February 2022 and are published on the Department's website.[52]
- KPM reports will be published twice a year, with the first report, published in August 2022, including information for the periods 1 July – 31 December 2020, 1 January – 30 June 2021 and 1 July – 31 December 2021.

Review of KPM for the 7CPA

Following completion of the first reporting cycle the Department will consult with PSCC representatives (Guild, PSA, CHF and NACCHO) as well as relevant program areas within the Department to review KPM for the 7CPA.

Assessment of the Remuneration Adjustment Mechanism (RAM)

Clause 3.5 of the 7CPA commits the Department and the Guild to assessing the fitness for purpose of the RAM by 30 June 2023. This work is expected to proceed during the third year of the 7CPA.

Assessment of Community Pharmacy Programs

Clause 9.6.2 of the 7CPA acknowledges that the Department will review Commonwealth funded services under Community Pharmacy Programs during the term of the 7CPA. Appropriate oversight and assessment of Community Pharmacy Programs funded under the 7CPA will occur to ensure that program outcomes continue to result in proper use of public resources. Such oversight will be supported via compliance activities undertaken by the Community Pharmacy Programs Administrator.[53]

The Department will otherwise undertake or commission an assessment of Commonwealth funded services under Community Pharmacy Programs during the 7CPA to identify and assess their outcomes, efficiency and effectiveness. Such an assessment may include seeking patient feedback.

As noted previously, the lack of evaluable data means that it is difficult to assess health outcomes from Community Pharmacy Programs. However, any increase in data collection also needs to be balanced with the increased burden this would incur on pharmacists and patients.

Review of CPCC and PSCC arrangements

Clause 16.4.2 of the 7CPA provides for the Department to conduct a review in the second year of the 7CPA of the arrangements for the CPCC and PSCC to assess their continued suitability. Initial discussions regarding this review were held with PSCC representatives at the fourth meeting of the PSCC, held on 15 June 2022.

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[52] www.pbs.gov.au/info/general/key-performance-measures-for-the-seventh-community-pharmacy
[53] www.ppaonline.com.au/compliance

Implications

The 7CPA continues to support arrangements for pharmacy remuneration, community pharmacy programs, and CSO funding arrangements and related services, consistent with previous successive CPAs.

As per previous CPAs, the 7CPA has been successful in centrally securing an agreement between Government and the community pharmacy sector for the continuation of remuneration for the dispensing of PBS medicines by approved pharmacists.

Stakeholders consulted during this PIR have consistently recognised that the 7CPA has been successful in supporting access to PBS medicines through a qualified network of community pharmacies that is valued by consumers. Further, 7CPA has provided a net benefit in terms of increasing access to community pharmacy programs; providing better support for regional, rural and remote pharmacies; and improving access to medicines for Aboriginal and Torres Strait Islander people.

By this measure, the 7CPA continues to be an appropriate mechanism for supporting access to PBS subsidised medicines and associated services in the Australian community.

This PIR has identified two key concerns to be addressed in future funding arrangements and program delivery:

- Lack of quality data to conduct a robust evaluation of the Agreement against expected outcomes.
- Paucity of collaborative relationship between signatories to the agreement and broader stakeholder groups.

Data collection and evaluation

In keeping with previous arrangements under the 6CPA, the Department continues to publish monthly service delivery and expenditure data for community pharmacy programs funded under the 7CPA. However, the scarcity and quality of available data for robust and meaningful analysis of health outcomes, in common with previous CPAs, is a continuing concern that has been highlighted through this PIR.

The development of KPM for the 7CPA was a step forward in evaluating the outcomes of the Agreement. However, the lack of funding allocated to evaluation activities under the Agreement has meant that reporting is reliant on already available data. As is evident from the first report on KPM for the 7CPA,[54] this has restricted the evaluation of 7CPA community pharmacy programs to reporting on details of service delivery and expenditure and not on patient outcomes. Whereas significant improvements to data collection and review activities might be indicated as a logical step to enable more robust and meaningful evaluation of activities funded under the 7CPA, it would be impractical to expect that Government and other signatories to the Agreement might commit to successful achievement of this goal within the timeframe of the current Agreement.

A robust evaluation framework should be funded under any future agreement to support the collection of quality data, in addition to that already available, to support a robust and meaningful analysis of the outcomes achieved from the agreement and the programs and

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[54] www.pbs.gov.au/info/general/key-performance-measures-for-the-seventh-community-pharmacy

services it funds. This would entail signatories to any future Community Pharmacy Agreement under which Community Pharmacy Programs and related services were to be funded to agree on appropriate allocation of funding to support such an evaluation framework. Whereas it would be most appropriate for this to be agreed between parties ahead of the commencement of any future arrangements post the current 7CPA, history has shown it unlikely that Government could achieve this in connection with and tied to the central activity of negotiating a scheme or level of remuneration for pharmacy dispensing of PBS medicines. In this sense the quality of evaluable professional pharmacy programs and services may continue to be hampered by being funded under the single umbrella of successive Community Pharmacy Agreements.

Data sources for robust evaluation

The impact of any program or service is shaped not only by the specifics and cost of the actual service delivered but also by the value created for patients or consumers who are recipients of the service and the context in which the service is delivered. For this reason, evaluation of the effectiveness of delivery of any service over time is essential.

New and continuing community pharmacy programs under the 7CPA can be broadly classified into programs that aim to improve medication adherence (such as Dose Administration Aids and Staged Supply of medicines) and medication management (such as MedsChecks, Home Medicines and Residential Medication Management Reviews).

Robust and meaningful evaluation of these services would appropriately require collation of both quantitative and qualitative data from providers of any service (community pharmacies) and patients receiving that service.

Data sources relevant to community pharmacies might include but not be limited to PBS script and other medicines supply data, pharmacy program registration and claims data, in addition to that already collected through the Pharmacy Programs online portal, and surveys and interviews with pharmacists delivering funded services.

Patients and consumers of services would also need to be engaged to provide relevant program evaluation data through interviews, surveys and other means to measure relevant clinical indicators, compliance levels, satisfaction levels with service delivery and outcomes, and health related quality of life indicators, at appropriate timepoints pre- and post-service.

In addition to the above data sources, data routinely collected by the Commonwealth via the Pharmacy Programs Administrator, Pharmaceutical Benefits and Medicare claims systems, as well as state and territory hospital admissions and treatment data may also be relevant for future consideration.

Given the breadth of the above data collection and monitoring activities, the need for genuine collaboration, agreement and coordination between stakeholders across governments, the sector and patient and consumer groups will be of key importance.

Consultation with stakeholders

While key stakeholders appear to be in general agreement that the 7CPA supports more inclusive formal consultation arrangements, stakeholders have raised concerns regarding the extent to which they are being genuinely consulted.

It must be noted that unlike previous CPAs, the 7CPA has taken steps to improve consultation and collaboration between stakeholders and improve transparency of governance processes. These are processes that will improve with time and effort. It must also be noted that the stakeholder consultation for this PIR report occurred at an early stage of the 7CPA, in particular given the constraints imposed by the COVID-19 pandemic. Since the early stakeholder consultation, the 7CPA consultative committees have collaborated to develop the first KPM report and committed to undertake assessment of specific 7CPA community pharmacy programs for their effectiveness.

The Department has noted the feedback provided by stakeholders through the PIR.

Future agreements

A theme that has emerged through this PIR is the suggestion that a single agreement may no longer be appropriate to address both dispensing remuneration and professional pharmacy services. This was also suggested by the Review of Pharmacy Remuneration and Regulation's Final Report[55] 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."*

Notwithstanding, stakeholders have recognised that there continues to be intrinsic value in the construct of successive five-year CPAs providing business certainty and guaranteed dispensing income across the community pharmacy sector.

It is notable that final negotiations and commencement of the 7CPA occurred when Australia was dealing with the initial stages of the COVID-19 pandemic. This is relevant from the perspective of community pharmacy being under increased demand, potentially having impacted delivery of certain professional services and programs provided under the 7CPA. Also of relevance is the range of additional pharmacy services and innovations funded outside of the 7CPA in response to COVID-19 (eg. Home Medicines Service, e-scripts, COVID-19 vaccination and Rapid Test Concessional Access programs) and the January 2020 bushfires and 2022 floods (eg. continued dispensing). Each of these programs serves as an example for Government supporting the role of community pharmacy as part of Australia's primary health care system independently of a multi-year agreement closely tied to the primary function of pharmacy dispensing revenue.

Ultimately, future decisions regarding the continuation of CPAs and the structure they may take remain a matter for Government and as such have not been assessed under this PIR.

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[55] www1.health.gov.au/internet/main/publishing.nsf/content/7E5846EB2D7BA299CA257F5C007C0E21/$File/review-of-pharmacy-remuneration-and-regulation-final-report.pdf

APPENDICES

1. Abbreviations

ACC	Agreement Consultative Committee
ACCHO	Aboriginal Community Controlled Health Organisation
ACPA	Australian Community Pharmacy Authority
the Act	*National Health Act 1953*
ADHA	Australian Digital Health Agency
AEMP	Approved Ex-Manufacturer Price
ANAO Audit	Australian National Audit Office's audit of the Administration of the
AOC	Agreement Oversight Committee
Compact	2017 Strengthening PBS Compact
CPA	Community Pharmacy Agreement
6CPA	Sixth Community Pharmacy Agreement
7CPA	Seventh Community Pharmacy Agreement
CHF	Consumers Health Forum of Australia
CMI	Consumer Medicines Information
CPCC	Community Pharmacy Consultation Committee
CPSF	Community Pharmacy Stakeholder Forum
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
IDAA	Indigenous Dose Administration Aids program
IHSPS	Indigenous Health Services Pharmacy Support program
KPM	Key Performance Measures

Location Rules	Pharmacy Location Rules
MSIA	Medicines Software Industry Association
NACCHO	National Aboriginal Community Controlled Heath 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
RIS	Regulation Impact Statement
RMMR	Residential Medication Management Review
RPBS	Repatriation Pharmaceutical Benefits Scheme
RPMA	Rural / Regional Pharmacy Maintenance Allowance
TGA	Therapeutic Goods Administration

2. Glossary

Term	Definition
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 *National Health Act 1953* 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
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 does 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

Term	Definition
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: • *Pharmacist Only Medicines* – which can only be supplied from a pharmacy on the advice of a pharmacist; • *Pharmacy Medicines* – which are available for self-selection from pharmacies only; or • *Non-Scheduled Medicines* – 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 *National Health Act 1593* (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 *National Health (Australian Community Pharmacy Authority Rules) Determination 2018 (PB 46 of 2018)*, 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 *National Health Act 1953*
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. Regulatory burden of new and amended Community Pharmacy Programs

The impact of regulatory changes under the 7CPA on key stakeholders namely, community pharmacy, consumers and government are examined below for the four new and revised community pharmacy programs implemented under the 7CPA: the Regional Pharmacy Maintenance Allowance (RPMA);[56] Indigenous Dose Administration Aids (IDAA) Program; Indigenous Health Services Payments Support (IHSPS) Program; and Closing the Gap (CTG) PBS Co-payment reforms.

Changes to pharmacy dispensing remuneration, wholesaler mark-up and supply funding arrangements, National Diabetes Service Scheme (NDSS) funding arrangements and other community pharmacy programs that were being continued in 7CPA from the 6CPA, are not expected to cause any change in regulatory burden for stakeholders. The 7CPA maintains the status quo for each of these activities ensuring continuity of these services for the duration of the 7CPA.

Table 13 below summarises regulatory burden estimates for new and amended community pharmacy programs under 7CPA. Further information is provided for each of these programs below.

Table 13. Regulatory Burden Estimates (RBE) for new and amended Community Pharmacy Programs under 7CPA

Average annual regulatory costs (from business as usual)				
Change in costs ($ million)	**Business**	**Community organisations**	**Individuals**	**Total change in costs**
RPMA	**6CPA:** $1,218 **7CPA:** $2,762	Nil	Nil	$1,544
CTG PBS Co-payment program	Not material	Nil	Nil	Not material
IDAA program	**6CPA:** n/a **7CPA:** $1,592,181	Nil	Nil	$1,592,181
IHSPS program	**6CPA:** n/a **7CPA:** $27,515	Nil	Nil	$27,515
Total, by sector	***$1,623,676***	***Nil***	***Nil***	***$1,621,240***

Both IDAA and IHSPS are new services under 7CPA and have no business as usual under 6CPA to compare against.

[56] Continuing from the 6CPA, the Rural Pharmacy Maintenance Allowance became the Regional Pharmacy Maintenance Allowance under the 7CPA, from 1 January 2021.

Regional Pharmacy Maintenance Allowance (RPMA)

This program consists of a monthly allowance paid to eligible owners of section 90 Approved Pharmacies[57] in regional, rural, and remote areas to support access to PBS medicines and pharmacy services for people living in these areas.

RPMA payments, introduced under the Third Community Pharmacy Agreement had, prior to changes made under the 7CPA, used the Pharmacy Accessibility/Remoteness Index of Australia (PhARIA) to provide a measure of physical and professional remoteness of pharmacies throughout Australia, to determine the applicable RPMA allowance for a specific pharmacy.

Under the 7CPA, from 1 January 2021, the basis for RPMA eligibility and payments was changed from the use of PhARIA categories to the Modified Monash Model (MMM) rural classification system, in line with arrangements agreed under the 7CPA. In contrast to PhARIA, the MMM classifies metropolitan, regional, rural and remote areas according to geographical remoteness, as defined by the Australian Bureau of Statistics (ABS), and town size and is better targeted to health workforce programs.

Who is affected?

Eligible community pharmacies need to apply to receive RPMA payments (a single-time application) followed by annual renewal and re-certification through the Pharmacy Programs Administrator (PPA) online portal to continue receiving payments. Pharmacies are easily able to confirm their MMM classification using the Health Workforce Locator[58] to submit an online application which would then be processed by PPA. Whereas, completing the required application or renewal processes online may possibly prevent a pharmacist from being able to perform their core dispensing functions for a small part of the day, these processes are identical to those followed under the 6CPA and therefore the regulatory burden is not material. The RPMA allowance payments made under the 7CPA currently range between $3,000 and $51,328 per annum for individual pharmacies.

During the last year of the 6CPA (2019-2020), 797 pharmacies received payments totalling $15,542,027, while in the first six months of 2022, under the revised arrangements under the 7CPA, there were an average of 1060 pharmacies receiving monthly RPMA payments amounting to on average $1.64 million in payments each month.

Following the program changes made on 1 January 2021, 22 pharmacies which had previously been receiving payments became ineligible for continuing RPMA payments. No remedial payments were made to these pharmacies.

Table 14 below provides details of RPMA program expenditure and the number of pharmacies accessing payments under 7CPA (pre- and post- program changes made on 1 January 2021). The change from PhARIA to MMM classification system has resulted in an increase of over 200 additional eligible rural and remote pharmacies accessing monthly RPMA payments within the first 6 months of the new arrangements.

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[57] Refers to a pharmacy premises from which a pharmacist approved under section 90 of the *National Health Act 1953* may dispense PBS subsidised medicines.

[58] www.health.gov.au/resources/apps-and-tools/health-workforce-locator

Table 14. RPMA expenditure and pharmacies receiving payments under 7CPA

Time period	Expenditure	Average no of pharmacies receiving monthly payments
1 July – 31 December 2020	$8,067,368 (PhARIA)	803
1 January – 30 June 2021	$9,347,083 (under MMM)	1006
Total expenditure (2020-21)	***$17,414,451***	
1 July – 31 December 2021	$9,831,038 (MMM)	1049
1 January – 30 June 2022	$9,893,154 (MMM)	1060
Total expenditure (2021-22)	***$19,724,192***	

Source: Seventh Community Pharmacy Agreement – Pharmacy Programs Data. Available at: www.health.gov.au/resources/publications/seventh-community-pharmacy-agreements-7cpas-pharmacy-programs-data

Regulatory burden

The changes to the RPMA program under the 7CPA have caused minimal change in regulatory burden to eligible pharmacies. The processes for application and re-certification by eligible pharmacies remain identical to the processes under previous arrangements under the 6CPA. The introduction of the PPA online portal from early 2019 under 6CPA had previously streamlined these processes for eligible pharmacies and no new reporting or compliance requirements have been introduced under the new program arrangements under the 7CPA. As discussed above any minimal time impost for eligible pharmacists in completing the online application or annual recertification is likely compensated by the monthly RPMA allowance received.

Whereas the changes to the RPMA program may have adversely impacted the business operations of the small number of pharmacies that became ineligible for RPMA payments, the change in classification system has enabled Government to better target RPMA payments to a greater number of pharmacies servicing rural and remote areas, thereby supporting the Government’s commitment under the 7CPA of supporting increased investment in services to regional, rural and remote communities across Australia.

Closing the Gap (CTG) PBS Co-payment program

The CTG PBS Co-payment program was initiated in July 2010 to improve access to affordable PBS medicines for Aboriginal and Torres Strait Islander people living with, or at risk of, chronic disease, and who in their doctor’s opinion would experience setbacks in the prevention or ongoing management of chronic disease or were at risk of non-adherence without assistance through the program. Patients eligible for this program are able to access their prescribed PBS medicines at the concessional rate or free of cost.

Under the 7CPA, the CTG Co-payment program underwent changes from 1 July 2021 to expand the outreach of these services. One of these changes was to enable Aboriginal and Torres Strait Islander patients to be registered for the program regardless of their chronic disease status and where in Australia they lived.

Table 15 below provides details of the total number of PBS items supplied and expenditure for the CTG PBS Co-Payment Program under the 7CPA across states and territories. Following the changes made on 1 July 2021 the number of PBS items supplied under the CTG Co-payment program has increased across all states and territories.

Table 15. Number of PBS Items and benefit amounts paid under CTG Co-payment measure during 7CPA

	1 July – 31 Dec 2020		1 Jan – 30 Jun 2021		1 Jul – 31 Dec 2021	
Pharmacy location	**PBS items supplied**	**CTG Benefits Paid**	**PBS items supplied**	**CTG Benefits Paid**	**PBS items supplied**	**CTG Benefits Paid**
ACT	30,804	$248,232	32,750	$321,403	36,572	$306,032
NSW	1,477,827	$9,355,195	1,477,735	$12,287,239	1,678,691	$10,933,459
NT	101,609	$787,196	106,058	$952,546	117,227	$912,899
QLD	1,102,805	$7,220,833	1,104,297	$9,224,925	1,349,344	$9,096,850
SA	245,503	$1,497,863	244,270	$1,936,499	269,215	$1,692,801
TAS	141,318	$778,427	143,941	$1,133,784	174,459	$1,011,864
VIC	277,473	$1,752,301	287,334	$2,381,214	331,688	$2,154,362
WA	398,363	$2,673,443	385,846	$3,272,666	460,586	$3,196,985
Total	***3,775,702***	***$24,313,491***	***3,782,231***	***$31,510,276***	***4,417,782***	***$29,305,252***

Information obtained from PBS online claims data maintained by the Department of Health and Aged Care and sourced from Services Australia. Data extracted 19 May 2022.

Who is affected?

These changes will be beneficial for Aboriginal and Torres Strait Islander people who may register for the program irrespective of where they live and their chronic disease status so long as their healthcare professional deems them eligible for the program. PBS prescribers will no longer need to annotate the prescriptions with 'CTG' and prescriptions issued by public hospitals may be dispensed at any community pharmacy of the patient's choosing.

The program changes also included a new centralised patient registration database through Services Australia under which any PBS prescriber or Aboriginal and Torres Strait Islander health practitioner may register eligible Aboriginal and Torres Strait Islander people, meaning that a patient's details would move with them irrespective of the clinic the patient was initially registered at.

Regulatory burden

Pharmacies are not involved in the registration process for patients and there is therefore no change in existing regulatory burden on pharmacies for dispensing CTG prescriptions.

Indigenous Dose Administration Aids (IDAA)

A Dose Administration Aid (DAA) is a well-sealed, tamper-evident device that allows individual medicine doses to be organised according to a patient's prescribed dose schedule.

The Indigenous Dose Administration Aids (IDAA) Program is a new community pharmacy program under the 7CPA, designed to assist Aboriginal and Torres Strait Islander patients in

the community to better manage their medicines, with the objective of avoiding medication misadventure and improving medication adherence. Specifically, the IDAA program is intended for use by Aboriginal and Torres Strait Islander patients for whom there is clinical evidence of non-intentional non-adherence and is not recommended simply for patient convenience.

The IDAA program closely follows the DAA Program which has been in operation since the Fourth CPA. The IDAA program commenced on 1 July 2021, but unlike the DAA program, is an uncapped program. Approved service providers receive a payment of $11.60 per IDAA without any additional patient charge. The DAA program on the other hand is subject to a weekly cap of 60 DAA services per pharmacy with a service provider receiving $6.17 per patient for a weekly DAA service.

Table 16 below shows the volume and expenditure of both the DAA and IDAA programs over the last eighteen months of the 6CPA and first eighteen months of the 7CPA – representing the first six months operation of the IDAA program.

Table 16. IDAA and DAA service provision and expenditure under 6CPA and 7CPA

	6CPA 1 Jan 2019 – 30 Jun 2020		7CPA 1 Jul 2020 – 31 Dec 2021	
Service	Services	Expenditure	Services	Expenditure
DAA Program	23,326,731	$138,523,353	23,684,947	$146,480,688
IDAA Program *	–	–	635,108	$7,433,675

** the IDAA program commenced on 1 July 2021*

The increased uptake of IDAA services without a concomitant decrease in DAA services is an indication of the improved access to DAA in people of Aboriginal and Torres Strait Islander origin afforded by the IDAA program.

Who is affected?

Aboriginal and Torres Strait Islander patients who may have had difficulties with medication adherence and who previously had or did not have access to a DAA service will benefit from access to the new IDAA program.

As in the case of the existing DAA program, community pharmacies will need to register to provide the IDAA program through the PPA online portal. The registration process for the IDAA program is separate to the registration process for the DAA program, with the notable requirement for pharmacies providing IDAA services to ensure that any registered pharmacist providing this service engages with prospective patients in a culturally sensitive manner. As such, pharmacies enrolling for the IDAA Program need to ensure that pharmacists providing this service undergo appropriate cultural awareness training, as well as maintaining connections with local Aboriginal and Torres Strait Islander organisations to ensure that services are provided in a culturally safe manner within these communities.

It is also a requirement that a pharmacist engaged in providing an IDAA service should not be involved in any other dispensing or professional duties during this service. There are also compliance requirements that pharmacies need to maintain in accordance with the IDAA

program rules which mean that a pharmacy providing both DAA and IDAA services would need to maintain parallel documentation for both services.

It is reasonable to assume that most pharmacies that already have DAA services in place would also be able to use the same DAA set up to provide IDAA services.

As this is a new service, there is no data available that can shed light on the cost of providing this service, but it can be assumed that the cost to pharmacy would be similar to the cost for providing a DAA with the exception that for most DAAs, there is an additional cost to the patient imposed by the pharmacy whereas patients do not incur any cost in receiving an IDAA service.

Regulatory burden

The red tape impact of initiating an IDAA service is considered not material as the process is near identical to the existing DAA service provided by pharmacies and which can be used for providing new IDAA services. As cultural competency training is now an inherent requirement of pharmacy education and training, it is assumed that pharmacies would already have staff available with appropriate cultural awareness training and as such this would not constitute a regulatory burden.

The monitoring and compliance requirements for the IDAA program are identical to those of the existing DAA program and are therefore considered to have minimal regulatory impact. Pharmacies are paid for the provision of an IDAA service and are expected to maintain appropriate records to acquit such service payment.

It is expected that for pharmacies with existing DAA services in place, there would be minimal burden in setting up facilities for the provision of an IDAA service.

Indigenous Health Services Pharmacy Support (IHSPS) Program

The IHSPS Program was created by merging the Quality Use of Medicines Maximised for Aboriginal and Torres Strait Islander People (QUMAX) and S100 Pharmacy Support Allowance programs, which continued from the 6CPA during the first year of the 7CPA (until 30 June 2021). The QUMAX Program helped to fund a range of support services by participating Aboriginal Community Controlled Health Organisations (ACCHOs) in rural and urban Australia. The S100 Pharmacy Support Allowance Program provided an allowance for community pharmacies and approved hospital authorities (under certain conditions) to provide a range of Quality Use of Medicines (QUM) services to Indigenous Health Services (IHS) participating in the Section 100 Remote Area Aboriginal Health Services (RAAHS) program. A 2017 review of Indigenous Pharmacy Programs undertaken by the Department recommended amalgamating certain disparate Indigenous pharmacy programs into one single cohesive program, namely the IHSPS Program.

The IHSPS Program provides additional support such as QUM pharmacist support, QUM devices, QUM education and patient transport services to IHSs and approved service providers to ensure better QUM health outcomes for Aboriginal and Torres Strait Islander people living in the community.

The funding provided to eligible program participants is based on an annual Work Plan providing the specific QUM objectives for each QUM support category. Program participants are also required to provide two Progress Reports for each program cycle, including financial

reporting (as appropriate) against the QUM Support categories outlined on the reporting template in the Work Plan. The PPA makes an initial payment to the program participant for 50% of the annual allocation for all QUM categories. This payment is made by the PPA once the Work Plan has been approved. The PPA will then make the two subsequent payments (equivalent to 30% and 20% of the yearly allocation, respectively) within 30 days of the PPA approving each Progress Report.

Table 17 and Table 18 below show the numbers of service providers (program participants) and expenditure for QUMAX, S100 Pharmacy Support Allowance and IHSPS Programs under the 6CPA and 7CPA. The IHSPS Program commenced in September 2021 and expended $1,958,321 to 31 December 2021.

Table 17. Number of participating service providers and expenditure recorded for QUMAX, S100 Pharmacy Support Allowance and IHSPS programs under 7CPA

	1 Jul – 31 Dec 2020		1 Jan – 30 Jun 2021		1 Jul – 31 Dec 2021	
Program	Providers	Expenditure	Providers	Expenditure	Providers	Expenditure
QUMAX	168	$1,113,236	168	$1,303,157	N/A	$60,415
S100 Support	51	$1,336,000	51	$501,375	N/A	$399,000
IHSPS	–	–	–	–	225	$1,958,321

Information sourced from Rural support and Aboriginal and Torres Strait Islander pharmacy programs data *published by the Department of Health and Aged Care. Available at:* *http://www.health.gov.au/resources/publications/seventh-community-pharmacy-agreement-7cpas-rural-support-and-aboriginal-and-torres-strait-islander-pharmacy-programs-data*

Table 18. Actual expenditure for QUMAX and S100 Support Allowance Programs in last year of 6CPA

	1 July 2019 – 30 June 2020
Program	**Expenditure**
QMAX	$4,944,085
S100 Support	$4,180,007

Information sourced from Rural support and Aboriginal and Torres Strait Islander pharmacy programs data *published by the Department of Health and Aged Care. Available at:* *http://www.health.gov.au/resources/publications/seventh-community-pharmacy-agreement-7cpas-rural-support-and-aboriginal-and-torres-strait-islander-pharmacy-programs-data*

Who is affected?

There are specific eligibility requirements that IHSs and community pharmacies (delegated service providers) need to adhere to be eligible for support under the IHSPS Program. Eligible IHSs or community pharmacies with delegated authority must register for the program annually and meet all relevant compliance requirements such as documentation, reporting and receipt of payments.

A clear advantage of the IHSPS program is that it enables support payments to be received directly by approved Aboriginal Health Services (should they prefer this), thereby allowing the local community to manage the program better tailored to local needs.

Regulatory burden

The annual red tape impact for all 225 eligible IHS service providers in 2021-22, is estimated as $27,515.24.[59] The annual funding allocation for each IHS consists of a base amount plus an additional amount for each IHS client. The base rate per participating IHS is $3000 with additional loading of $3000 per outstation and client allowance based on the formula:

IHS Annual Budget = Base Rate + Approved Outstation Loading (if applicable) + Client Allowance.

Further details regarding the IHSPS payment model can be found on the PPA website at: www.ppaonline.com.au/wp-content/uploads/2022/05/22-23-IHSPS-Payment-Model-Factsheet.pdf.

The true regulatory impact of this program will only be clear with passing time. For participating service providers, there are clear reporting and monitoring requirements which constitute a regulatory burden. These requirements are necessary to ensure that funds are being utilised in accordance with IHSPS Program requirements.

[59] Red tape impact for initial Workplan submission = 225 (no. of IHSs) x 1 (time in hours) x $34.94 x 1.75 = $13,757.62; Red tape impact for two progress reports = 225 x 1 (2 x 30min) x $34.94 x 1.75 = $13,757.62; Total annual red tape impact = $27,515.24.