

IMPACT ANALYSIS

REDUCTION OF THE PHARMACEUTICAL BENEFITS SCHEME (PBS) GENERAL PATIENT CO-PAYMENT TO \$25

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Executive Summary

This Impact Analysis (IA) supports Government consideration of a reduction to the Pharmaceutical Benefits Scheme (PBS) general co-payment. This IA addresses all seven questions of the Australian Government Guide to Policy Impact Analysis. A draft was considered in the 2025-26 Budget context.

The PBS is a key aspect of the National Medicines Policy¹ which promotes the quality use of medicines and medicines safety to meet the current and future health needs of the community. The PBS provides timely, reliable and affordable access to necessary medicines for Australians.

Under the PBS, the government subsidises the cost of medicine for most medical conditions. A copayment is the amount of money a patient pays for their PBS medicines. This amount is usually a small proportion of the cost of the medicine and the Australian Government pays the rest. Many PBS medicines can cost hundreds or even thousands of dollars per prescription. Some medicines on the PBS can also cost less than the co-payment, in which case patients pay the full cost. If patients need a lot of medicines, the PBS Safety Net can also help to keep costs down. Patients pay less for medicines (or pay nothing) where their PBS costs reach the relevant threshold amount.

For many Australians, medicines are a significant cost of living pressure, affecting women at almost twice the rate of men. In 2023-24, nearly 1.2 million Australians delayed or did not fill a prescription because of cost. These patients are almost twice as likely to be in poor health, requiring PBS medicines to treat chronic conditions. Not taking medicines can negatively impact the health of these people and could lead to higher government costs due to their worsening health, such as increased likelihood of acute hospitalisations.

To improve affordability of medicines for 5.1 million Australians, during the 2025 Federal Election, the Australian Labor Party committed to providing:

...cost of living relief to millions of Australians by making medicines even cheaper. From 1 January 2026, the maximum cost of a prescription for a Pharmaceutical Benefits Scheme (PBS) medicine will be cut from \$31.60 to $$25.^2$

This commitment was based on years of advocacy from a range of stakeholders, including the Pharmacy Guild of Australia³. As the proposed co-payment reduction was announced as an election commitment, considerable public scrutiny and consultation about the proposal occurred in through the 2025 Federal election.

This analysis compares the general patient co-payment reduction to \$25 against the status quo. Under the status quo the general patient co-payment – which has been \$31.60 since 1 January 2025 – would continue to be indexed annually from 1 January 2026.

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

² Australian Labor Party, 'Strengthening Medicare' (2025) https://alp.org.au/strengthening-medicare/

³ New campaign to bring down the cost of medicines - The Pharmacy Guild of Australia

Option 1: Continuation of the current general patient co-payment, which would be \$31.60 plus any relevant indexation amount, as of 1 January 2026 (Status Quo).

Option 2: Reduce the general patient co-payment amount from \$31.60 (July 2025) to \$25 from 1 January 2026, with indexation continuing as per current arrangements from 1 January 2027.

The analysis considers the number of prescriptions historically dispensed that were below and above the new co-payment amount, the impact of the co-payment at various levels to competition in the market, the impact of the co-payment reduction on allowable discounts and incentives, the interaction of the co-payment and the Safety Net, and the impact on the PBS expenditure and revenue.

Compared to Safety Net changes, a co-payment reduction is superior to assist with cost-of-living pressures as patients will pay less at the counter for each prescription without needing to spend more to access cheaper medicines. Savings will accumulate with every above co-payment prescription filled prior to reaching the threshold, and these savings will exceed the value of any savings foregone on prescriptions that no longer reach the threshold. For patients who still exceed the safety net threshold after the general co-payment reduction, the cost of prescriptions that exceed the threshold is unchanged. PBS data shows that less than 1% of general patients utilised the Safety Net in 2023 and 2024.

Patients who are part of the Closing the Gap program won't have to pay more to reach the general patient PBS Safety Net threshold. Closing the Gap prescriptions priced at or above \$25.00 will continue to count toward the PBS Safety Net at the 2022 general patient co-payment amount of \$42.50, rather than at a reduced amount after the co-payment is lowered to \$25.00.

General patients will save \$784.6 million over four years from 2025-26, and \$236.9 million per year ongoing from 2029-30.

Reducing the co-payment will result in increased government expenditure of \$689.1 million over four years from 2025-26, and \$204.8 million per year ongoing from 2029-30. The \$25 reduction provides immediate cost of living relief to over 5.1 million general patients while also ensuring the PBS remains a sustainable investment for government. This level of investment was selected to ensure it does not come at the expense of priorities such as:

- continued listing of new medicines on the PBS,
- investment in other essential health services, such as bulk billing, and
- a competitive and sustainable pharmaceutical market.

The Government has a responsibility to ensure that the PBS is managed in a fiscally responsible and sustainable way, so that the Australian community can continue to be able to access affordable medicines into the future.

Pharmacists have had the option to provide a discretionary increased discount to general patient prescriptions for eligible medicines since 1 January 2023. Medicines that were discounted before a co-payment reduction can still be discounted after a co-payment reduction, ultimately discounting is

commercial a decision for pharmacies. Given the discretionary increased discount has only been in place since 1 January 2023, when the first co-payment reduction commenced, it is not possible to assess this policy before vs. after the co-payment reduction. However, PBS data shows that only a small proportion (6%) of general non-Safety Net prescriptions had a discount applied (either the pre-existing \$1 'allowable discount' and the newer 'discretionary discount'). Analysis also demonstrated that benefits to almost all patients of reducing the co-payment to \$25 would far exceed any loss due to potential discount reductions by pharmacies.

Investment in the PBS generates a level of revenue from pharmaceutical companies who have a Deed of Agreement (Deed) with the Commonwealth for a special pricing arrangement. These arrangements are generally requested by medicine sponsors. They ensure Australia can have access to medicines at prices recommended by the Pharmaceutical Benefits Advisory Committee as cost-effective (as required by the Act) without affecting the company's pricing of the product in other global markets. These arrangements are managed through rebates (the Government pays the full public price of the medicine through the supply chain when the medicine is dispensed, and then the medicine company rebates the Government later for the difference between the public price and the cost effective price for the medicine).

Changes to policy that change PBS expenditure can impact these arrangements – either reducing or increasing the amount pharmaceutical companies pay under the rebate. A co-payment reduction increases the amount pharmaceutical companies pay, with the actual amount being dependent on a range of other factors including the volume of product dispensed after the change.

The impact on pharmaceutical companies is estimated to be a cost of \$95.5 million over 4 years from 2025-26, and \$31.6 million per year ongoing from 2029-30.

When entering a Deed, sponsors specifically agree that the Deed continues to operate without modification in the event of a Price Variation (as defined in the Deed). Special pricing arrangements are maintained by the Department on behalf of sponsors, and it is open to sponsors to exit these arrangements at any time.

Background

The National Medicines Policy

Australia's 2022 National Medicines Policy⁴ (NMP) is a high-level framework focused on the availability and the use of medicines and medicines-related services. The NMP relates to medicines research and development, manufacture, regulation, evaluation, supply, dispensing, storage and access. It promotes the quality use of medicines and medicines safety by focusing on the current and future health needs of people and the responsibilities of all partners to achieve the best health, social and economic outcomes for all Australians.

The NMP identifies and brings together all partners around a common aim and a shared responsibility for policy stewardship. The NMP acknowledges the fundamental role of consumers in achieving the policy aim by placing the individual at the centre, and by focusing on and responding to the needs of Australia's diverse population.

The central pillars of the NMP, and the intended outcomes are:

Central Pillar	Intended Outcome
Equitable, timely, safe and reliable access to medicines and medicines -related services, at a cost that individuals and the community can afford	Medicines and medicines-related services are affordable and accessible in an equitable, timely and safe manner, leading to the achievement of the best health, social and economic benefits for all Australians.
Medicines meet the required standards of quality, safety and efficacy	 Australia's medicines regulatory processes are efficient, protect health and safety and are trusted by the community. Medicines are safe and effective, and their labelling and supporting information is readily available and supports the safe and quality use of medicines.
Quality use of medicines and medicines safety	 Individuals, their families and/or carers are empowered to actively participate in shared decision-making in relation to the safe and quality use of medicines and medicines-related services in the prevention, management and treatment of a specific health condition or indication and for the maintenance of good health. Adopting a person-centred approach, health professionals commit to, are trained and proactively supported to implement programs and initiatives to achieve the safe and quality use of medicines.
Collaborative, innovative and sustainable medicines industry and research sectors with the capability, capacity and expertise to respond to current and future health needs.	• Thriving, dynamic medicines industry and research sectors that are proactively supported to contribute to meeting current and future health needs in Australia and internationally. The sectors work within a positive, sustainable and responsive policy environment that delivers and promotes world-class innovation, including encouraging the development and commercialisation of medicines, new technologies and related services.

⁴ https://www.health.gov.au/sites/default/files/2022-12/national-medicines-policy.pdf

Central Pillar	Intended Outcome
	• A diverse medical research sector that generates high-quality evidence, strategies, systems and processes, which support ongoing improvements in the quality use of medicines and medicines safety.
	• Collaborative, robust, efficient, and reliable supply chains and networks that deliver equitable, timely, affordable and safe access to medicines and medicines-related services throughout Australia.

The Pharmaceutical Benefits Scheme (PBS)

The PBS is a national, government-funded scheme that subsidises the cost of a wide range of medicines for all Australians. The PBS is a key program supporting the delivery of the National Medicines Policy. This aims to achieve positive health results that matter to people and their communities and make sure all Australians have timely, safe and reliable access to effective, high-quality medicines.

The PBS is the primary mechanism through which the government subsidises access to prescription medicines, and is a key component of Medicare, providing significant direct assistance — \$18 billion in 2023-24 — to make medicines affordable. The PBS is intended to provide all eligible Australians with reliable, timely, and affordable access to high-quality, cost-effective medicines by subsidising the cost of medicines. The policy objective is to make medicines as affordable and accessible as possible to encourage consumers to use medicines prescribed to treat their health conditions. This can be important from an economic perspective as there can be more significant health system implications if treatments are delayed or not used as intended.

Under the PBS, the government subsidises the cost of medicine for most medical conditions. The government has a responsibility to ensure that the PBS is managed in a fiscally responsible and sustainable way, so that the Australian community can continue to be able to access affordable medicines into the future. To assist in achieving sustainability of the PBS, patients contribute a co-payment and the government pays the remaining cost. Many PBS medicines cost significantly more than the patient contribution.

The PBS Schedule lists all the medicinal products available under the scheme and explains the conditions for which they can be subsidised. The operation of the PBS is established under Part VII of the *National Health Act 1953* (Act). The PBS is available to all Australian residents who hold a current Medicare card. Overseas visitors from countries with which Australia has a Reciprocal Health Care Agreement are also eligible to access the scheme.

As of 30 June 2024, 930 different medicines were listed on the PBS, across 5,164 brands. In 2023-24, 226.5 million PBS subsidised prescriptions were dispensed, representing an increase of 1.5% compared to 2022-23. In total, patients contributed \$1.6 billion to the cost of their medicines, representing 8.4% of total medicine cost. Concession card holders received 199.0 million (87.8%)

⁵ Department of Health, Disability and Ageing, 2023-24 Annual Report (2024) pg. 65.

https://www.health.gov.au/sites/default/files/2024-10/department-of-health-and-aged-care-annual-report-2023-24.pdf Department of Health, Disability and Ageing, Negotiation of New Community Pharmacy Agreement: Impact Analysis (2024) pg. 25. https://oia.pmc.gov.au/sites/default/files/posts/2024/06/Impact%20Analysis.pdf

subsidised prescriptions, accounting for \$10.8 billion (60.9%) of total government expenditure. The government contributed \$54.34 towards the cost of each concession cardholder medicine on average. General patients received 27.1 million (12.0%) subsidised prescriptions, accounting for \$6.8 billion (38.3%) of government expenditure. The government contributed \$250.60 towards the cost of each general patient medicine on average.⁷

The Repatriation Pharmaceutical Benefits Scheme (RPBS) is administered by the Department of Veterans' Affairs (DVA), and can be used by veterans who have a DVA White, Gold or Orange Card.

PBS Co-payments

Under the PBS, general patients are those who have a Medicare card but do not have a Commonwealth concession card. Concessional patients have a Medicare card and a Commonwealth concession card, such as a:

- Pensioner Concession Card
- Commonwealth Seniors Health Card
- Health Care Card
- Repatriation Health Card for All Conditions (gold): concessional patients under RPBS
- Repatriation Health Card for Specific Conditions (white): only regarded as concessional
 patients for RPBS prescriptions unless they hold a separate entitlement from Centrelink,
 otherwise they are general patients
- Repatriation Pharmaceutical Benefits Card (orange): concessional patients under RPBS
- Safety Net Concession Card or Safety Net Entitlement Card.⁸

For 2025, the maximum cost for a PBS medicine is \$31.60 for general patients (the general patient co-payment) and \$7.70 for concession card holders (the concessional patient co-payment), plus any applicable special patient contribution, brand premium or therapeutic group premium.

In previous years, co-payments and Safety Net thresholds have been indexed in January each year in line with the Consumer Price Index (CPI). However, as part of the 2024-25 Budget, from January 2025, concessional co-payment indexation was frozen for five years, and indexation for the general patient co-payment was frozen for one year.⁹

From 1 January 2023, for the first time in 75 years, the general patient co-payment was reduced from \$42.50 to \$30.00, and a discretionary discount was introduced. Since 1 January 2023 and up until the end of June 2025, patients saved an estimated \$758,299,154 in total from this co-payment reduction.

https://www.health.gov.au/sites/default/files/2024-05/budget-2024-25-cheaper-medicines 0.pdf

⁷ Department of Health, Disability and Ageing, *PBS Expenditure and Prescriptions Report 1 July 2023 to 30 June 2024* (2024) pg. ii. https://www.pbs.gov.au/statistics/expenditure-prescriptions/2023-2024/PBS-Expenditure-prescriptions-report-2023-24.PDF

B Department of Health, Disability and Ageing, 'PBS Explanatory Notes: 1.4 Patient Charges' (2024)
 https://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section 1 4 Explanatory Notes
 Department of Health, Disability and Ageing, '2024-25 Budget - Cheaper Medicines (2024)

The Closing the Gap (CTG) PBS Co-payment Program improves access to affordable PBS medicines for First Nations people living with, or who are at risk of, chronic disease and who in their doctor's opinion would experience setbacks in the prevention or ongoing management of chronic disease if they did not take their prescribed medicine and would be unlikely to adhere to their medicines regimen without assistance through the program. Under the CTG PBS Co-payment Program, eligible First Nations people who are registered on the CTG PBS Co-payment Register and who would normally pay the full general PBS co-payment amount, pay the concessional rate when obtaining PBS medicines. Eligible patients who would normally pay the concessional rate receive their PBS medicines for free without having to pay a co-payment.¹⁰

PBS Safety Net

The PBS Safety Net protects patients and their families that require a large number of PBS, RPBS or non-PBS public hospital outpatient medicines. The same general or concessional Safety Net threshold is applied to a family unit regardless of whether the unit consists of an individual, a couple or a family with dependent children. For the purposes of the PBS, the family includes:

- the person
- the person's partner or de facto partner
- children under the age of 16 who are in the care and control of the person
- full-time students under the age of 25 who are dependent on the person. 11

The Safety Net thresholds are dollar amounts reached through the accumulation of eligible patient out-of-pocket (OOP) costs. Not all patient OOP costs for PBS medicines contribute to their Safety Net, for example optional 'additional fees' charged by pharmacies and brand premiums. When a patient exactly meets or exceeds the threshold in a calendar year, they can be issued with a:

- Safety Net Concession Card for general patients, where the co-payment is reduced to \$7.70 for the rest of the calendar year, or
- Safety Net Entitlement Card for concessional patients, where no co-payment applies and PBS medicines are provided for free for the rest of the calendar year.

The Safety Net threshold is reached by accumulating eligible patient contributions for PBS prescriptions supplied through community pharmacies, private hospitals, and PBS/RPBS and non-PBS medicines from the outpatient pharmacy of a public hospital. PBS/RPBS benefits (including authority items) can only be counted towards the Safety Net threshold when prescribed and supplied according to PBS conditions. A medicine supplied by a community pharmacist not approved to supply PBS benefits cannot count towards the Safety Net. Prescriptions for some PBS items are not eligible for Safety Net benefits if re-supplied as an 'early supply', i.e. within a specified period after a previous supply of the same or an equivalent item for the same person. The patient contribution for

¹⁰ Department of Health, Disability and Ageing, 'Closing the Gap (CTG) PBS Co-payment Program' (2025) https://www.pbs.gov.au/info/publication/factsheets/closing-the-gap-pbs-co-payment-measure

¹¹ Department of Health, Disability and Ageing, 'PBS Explanatory Notes: 1.5 The Safety Net Scheme' (2024) https://www.pbs.gov.au/info/healthpro/explanatory-notes/section1/Section 1 5 Explanatory Notes

an early supply does not count towards the Safety Net threshold. Brand premiums, therapeutic group premiums and special patient contributions do not count towards the Safety Net thresholds. ¹²

There are two Safety Net thresholds. From 1 January 2025, the general patient Safety Net threshold is \$1,694.00. When a person's and/or their family's total eligible payments for PBS and non-PBS public hospital outpatient prescriptions exactly meets or exceeds this amount, they may apply for a Safety Net Concession Card. They then pay the concessional co-payment amount of \$7.70 plus any applicable premium for PBS benefits for the rest of that calendar year. However, a general patient is eligible to receive concessional benefits once they have reached the Safety Net threshold, irrespective of whether they have been issued with a Safety Net Concession Card or not.

In January 2025, the government announced changes to how PBS Safety Net benefits would be applied to prescriptions which exactly meet the Safety Net threshold. Prior to this, co-payments were only reduced for prescriptions which exceeded the threshold. Patients who have been overcharged co-payments are entitled to a refund from Services Australia under section 87A of the Act.

60 Day Dispensing

From 1 September 2023 patients with chronic, stable medical conditions can be prescribed and dispensed a 60-day supply of medicine (rather than a 30-day supply) for eligible PBS items¹³. This change reduces the amount people pay for medicines and means fewer visits to the doctor and pharmacist. The implementation of 60-day dispensing occurred over three phases in 12 months.

Concessional patients can receive 60 days' medication for the cost of 30 days and only pay a single \$7.70 co-payment. For general patients with PBS items costing:

- \$31.60 or more receive 60 days' medication for the cost of 30 days and only pay a single \$31.60 co-payment.
- less than \$31.60 patients will not pay the same amount as for 30 days but will usually pay less than the cost for 60 days.

Any applicable brand premiums are not included in the cost savings for 60-day prescriptions and still need to be paid by the patient.¹⁴

Since 1 September 2023 and up until the end of June 2025, patients saved an estimated \$247,204,792 in total from this reform (\$136,969,604 saved by general patients and \$110,235,188 by concession patients).

Medicines must be considered by the Pharmaceutical Benefits Advisory Committee to be added to the list of 60-day dispensed medicines.

¹² DoHDA, 'PBS Explanatory Notes: 1.5 The Safety Net Scheme'.

¹³ https://www.pbs.gov.au/browse/60-day-dispensing

¹⁴ DoHDA, PBS Expenditure and Prescriptions Report 1 July 2023 to 30 June 2024, pg. vii.

Pharmacy Discounting

Since 1 January 2016 pharmacists could choose to discount the PBS patient co-payment by up to \$1.00 for each PBS medicine they supply above the relevant co-payment amount. The discount is not mandatory; it is at the pharmacist's discretion whether they would like to provide a discount and absorb its cost. The discretionary nature of the discount provides for pricing difference and competition between pharmacies on medicines priced above the relevant co-payment amount.

The \$1 discount was introduced to enhance competition between pharmacies. However, some stakeholders considered that it had not led to equitable outcomes, as it was more likely to be applied to some patients (those that hold a concession card) and in urban areas. The sector's response to the policy was mixed from introduction, with some stakeholders concerned about its impacts on community pharmacies, and its reliance upon market competition producing potentially inequitable results for patients living in rural and regional settings with minimal competition. Other stakeholders praised the policy's introduction, noting the ability to offer cheaper medicines to Australian patients with minimal impacts upon the taxpayer.¹⁵

Since 1 January 2023 (when the general co-payment was reduced to \$30), pharmacists have had the option to provide an additional discretionary increased discount to general patients for specific eligible medicines. This is not mandatory, and it is the pharmacist's choice to provide a discount, as it makes the prescription an unsubsidised prescription.

To be eligible for the increased discount the prescription must:

- be an ordinary prescription for a general patient; and
- have a Commonwealth price above or equal to \$31.60 (the current co-payment amount) and up to or equal to \$49.50 (the original co-payment amount indexed over time). Both amounts will be normally indexed over time (noting the general co-payment, and therefore the lower range amount, was frozen at \$31.60 for 2025). Under Option 2, from 1 January 2026, the eligible range for the discretionary discount will automatically expand to the new co-payment amount of above \$25 (and up to \$49.50).

Pharmacies can set any price they want for a medicine priced under the general patient co-payment, but formal discounts do not apply for prescriptions that are priced below the co-payment amount.

The discretionary discount is relative to the 'current' co-payment amount, whatever that may be. Pharmacies can continue to apply a discretionary discount to eligible general patient medicines after a change in the co-payment.

The discretionary discount is not compulsory. While medicines that were discounted before the copayment reduction can still be discounted after the co-payment reduction, ultimately discounting is commercial a decision for pharmacies. Pharmacies are encouraged to offer it where they can. As pharmacies can choose to provide a discount, and the amount of that discount, the price of medicines may vary depending on the pharmacy.

¹⁵ Department of Health, Disability and Ageing, *Negotiation Of New Community Pharmacy Agreement: Impact Analysis – Addendum 1: Optional \$1 Discount* (2024) https://oia.pmc.gov.au/sites/default/files/posts/2024/06/Addendum 0.pdf

Given discretionary increased discount has only been in place since 1 January 2023, when the first co-payment reduction commenced, it is not possible to assess this policy before the co-payment reduction. Instead, take-up of the discretionary increased discount was analysed.

From 1 January 2025, phase out of the \$1.00 allowable discount commenced, while annual adjustments to the PBS patient co-payment amounts in line with the CPI are frozen. It decreases by the amount of indexation (in dollars) that would have applied to a patient's PBS co-payment until it reaches zero. In 2025, the allowable co-payment discount for concessional patients is \$0.80, and \$0.10 for general patients.¹⁶

PBS data shows that in 2024, over 1.4 million (6%) general non-Safety Net prescriptions had either a pre-existing \$1 'allowable discount' and the newer 'discretionary discount' applied. Analysis was unable to distinguish between the discount types. Almost all discount amounts, across both discount types, were less than or equal to \$1. Only around 2,500 (0% of eligible prescriptions) of the discount amounts exceeded \$1. This means that the benefit to almost all patients of reducing the co-payment to \$25 would far exceed any loss due to potential discount reductions by pharmacies.

Deeds of Agreement

Deeds of Agreement are commercial agreements between the government and pharmaceutical companies. There are two broad types of arrangements which are covered by a deed: Special Pricing Arrangements (SPA) and Risk Sharing Arrangements (RSA).¹⁷ As at June 2025, there were 316 active Deeds of Agreement between the Commonwealth and pharmaceutical companies.

RSAs are designed to address risks relating to overall PBS expenditure from uncertainty associated with listing a medicine on the PBS. Such uncertainty arises in estimating utilisation and financial implications because potential for the medicine's usage differs from expectations, and usage that extends beyond the restriction.

RSAs generally involve the government recovering a percentage of expenditure from medicine sponsors once an agreed subsidisation cap has been exceeded. In practice, the RSA subsidisation cap represents a restriction specifying continuation or stopping rules for subsidisation of the medicine, or a Managed Access Program, or a combination of these two approaches. The cap is usually expressed as a dollar amount and the reimbursement percentage will vary depending on the level of risk. In many cases these caps are designed to encompass the extent of use estimated for the PBS restriction and the deed will include clauses that allow for the possibility of new medicines entering the market. This ensures fairness and encourages competition.

¹⁶ DoHDA, 'About the PBS'.

¹⁷ Department of Health, Disability and Ageing, *Guidelines for Deeds of Agreement for the Pharmaceutical Benefits Scheme (Version 1.5)* (2020) https://www.pbs.gov.au/industry/listing/elements/deeds-agreement/attachment-a-pdf-printable-version-of-guidelines-for-deeds-of-agreement-for-the-pbs.pdf

¹⁸ DoHDA, Guidelines for Deeds of Agreement for the PBS.

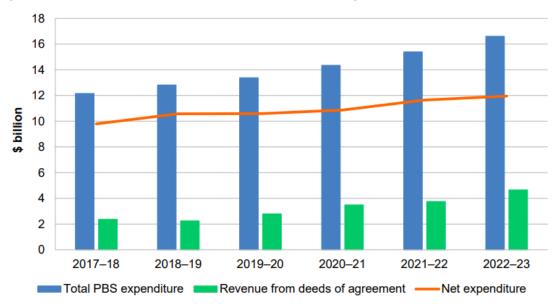


Figure 1 PBS Expenditure and Revenue from Deeds of Agreement, 2017-18 to 2022-23.

Factors affecting uncertainty¹⁹ (non-exhaustive)

Factors may arise from epidemiological data, pharmacoepidemiological data, expert opinion and assumptions. The uncertainties relevant to a particular medicine are considered through the Health Technology Assessment process.

Factors that could affect the extent of usage within the requested restriction include:

- Promotion might result in greater identification of the proposed medicine, resulting in more prescribers considering patients for treatment.
- Indirect media exposure might result in some consumers being more aware of the proposed medicine and seeking treatment with it. These patients might not be identified through the assessment process if a treated prevalence approach has been used.
- Outcomes of related research might have a positive or negative effect on uptake of the proposed medicine. The effects could emerge at the time the submission is lodged or within six years of listing.
- More prescribers and patients might seek treatment if the proposed medicine treats a
 medical condition for which the alternatives are substantially inferior to the proposed
 medicine (e.g. in terms of effectiveness, tolerability, patient acceptability, convenience).
- Limited access to designated types of PBS prescribers or to designated diagnostic procedures in a requested restriction might limit uptake and usage.
- The duration of therapy might be longer than expected from the randomised trials, particularly if trials are truncated.
- Patients might be treated more or less often than expected, particularly in the case of medical conditions with episodic manifestations.

¹⁹ Department of Health, Disability and Ageing, *Guidelines for Deeds of Agreement for the Pharmaceutical Benefits Scheme (Version 1.5)* (2020), https://pbac.pbs.gov.au/section-4/4-6-identification-estimation-and-reduction-of-uncertainty.html

- There might be a likelihood of doses varying over time from those expected from the controlled treatment in randomised trials.
- Epidemiological or market-share trends may have been inaccurately forecast.

Factors that could affect the likelihood of usage beyond the requested restriction are provided below. Some of the factors listed in the previous subsection might also affect the likelihood of usage beyond the requested restriction. Many of these factors relating to the requested restriction could be more applicable to risk-sharing arrangements.

- The requested restriction is for a subset of the types of patients who are eligible according to the TGA-approved indication(s).
- The requested restriction is for a subset of the types of patients who were eligible for the randomised trial(s) published for the proposed medicine, or there are randomised trials demonstrating evidence in other medical conditions.
- The requested restriction is for a subset of the types of patients who have been subsidised by the sponsor before lodgment of the submission (e.g. on compassionate grounds or as part of clinical studies).
- The requested restriction is for a subset of the types of patients for whom the sponsor plans to promote use of the proposed medicine before or after PBS listing.
- The requested restriction is for a subset of the types of patients who have the underlying medical condition.
- Prescribers could find it difficult to determine eligibility for the proposed medicine (eg a
 difficult differential diagnosis, ambiguity in the wording of the restriction, poor precision or
 accuracy in a diagnostic test), which might result in the misclassification of patients as
 eligible.
- Patient advocacy groups may have an influence on determination of eligibility by prescribers.

It might not be necessary to address any or all uncertainties associated with listing of a medicine, because the uncertainties might be very small or of little importance to the overall cost to the PBS.

Depending on the relevance of the uncertainty, the Pharmaceutical Benefits Advisory Committee (PBAC) may recommend an RSA be established as a condition of listing the medicine, which is then implemented through a Deed. In some instances, the sponsor may propose a risk-sharing arrangement (RSA) to enable access to a proposed medicine, while addressing uncertainties.

SPAs are generally requested by medicine sponsors and ensure Australia can have access to medicines at prices recommended by the PBAC as cost-effective (as required by the Act) without potentially affecting the company's pricing of the product in other global markets²⁰. Due to international reference pricing or various other commercial reasons, sponsors form the view that they are unable to supply the medicine at a particular publicly available price and seek to formalise a 'published' versus 'effective' price through the confidential SPA deed.

Under section 85E of the Act, the Minister of Health may enter deeds with pharmaceutical manufacturers to allow them to reimburse the government in relation to the provision of PBS

²⁰ DoHDA, Guidelines for Deeds of Agreement for the PBS.

benefits. The department uses SPA Criteria²¹ to guide the negotiation of SPAs. The main reason for the government to enter a SPA for the supply of a medicine is so that Australia can have access to medicines at a cost-effective price.

The difference between the published price in the Schedule of Pharmaceutical Benefits and the price actually paid by the government (the 'effective' price), is managed through a rebate arrangement. The SPA rebate percentage reflects the difference between the effective/supplied prices and other costs associated with the supplied medicines including dispensing fees, mark-ups and patient copayments prevailing at the time of listing. The co-payment used in this calculation is based on the composition of the expected patient population, which is only one factor in the calculation, and is in reference to Commonwealth Expenditure as defined in the deed²². The co-payment is generally a small fraction of the actual cost of the medicines that are subject to a Deed of Agreement.²³

The patient population of the PBS (by prescriptions in 2023-24) is 85% concessional patients and 12% general patients (with the balance Repatriation PBS patients). This translates to weighted average co-payment of \$7.76. Given the patient population is heavily skewed towards concessional patients, the impact of general patient co-payment changes on the weighted average co-payment is comparatively small. The impact of general patient co-payment changes on individual SPAs will vary depending on the specific patient population for that medicine.

When entering a Deed, sponsors specifically agree that the Deed continues to operate without modification in the event of a Price Variation (as defined in the deed²⁴), which includes variation in the co-payment. PBS policy, and therefore Commonwealth Expenditure, changes over time based on the priorities of the Government of the day. Deeds have accommodated regular changes to co-payments (Figure 2) and have not been varied when co-payment amounts change.

²¹ https://www.pbs.gov.au/industry/listing/elements/deeds-agreement/Special-Pricing-Arrangement-criteria.p

²² https://www.pbs.gov.au/industry/listing/elements/deeds-agreement/attachment-b-basic-deidentified-deed.pdf

²³ DoHDA, Guidelines for Deeds of Agreement for the PBS.

²⁴ https://www.pbs.gov.au/industry/listing/elements/deeds-agreement/attachment-b-basic-deidentified-deed.pdf



Figure 2 General and Concessional Co-payment Changes, 1960-2023.25

Deeds of agreement have standard clauses which cannot be amended unless PBAC or the government identifies that medicines require different treatment. Deeds are reviewed at the end of their term or after a PBAC recommendation to review. ²⁶ Special pricing arrangements are maintained by the Department on behalf of sponsors and it is open to sponsors to exit these arrangements at any time.

²⁵ https://www.pbs.gov.au/info/healthpro/explanatory-notes/front/fee

²⁶ ANAO, Administration of the Pharmaceutical Benefits Scheme, pg. 58.

Impact Analysis

1. What is the problem this proposal will solve?

The PBS subsidises access to prescription medicines, and is a key component of Medicare, providing significant direct assistance — \$18 billion in 2023-24 — to make medicines affordable. The PBS is intended to provide all eligible Australians with reliable, timely, and affordable access to high-quality, cost-effective medicines by subsidising the cost of medicines.

Policy Problem

Some Australians are not taking their prescribed medicines because they cannot afford to buy them, particularly in the current context of higher cost of living pressures including an increase in expenditure on healthcare²⁷.

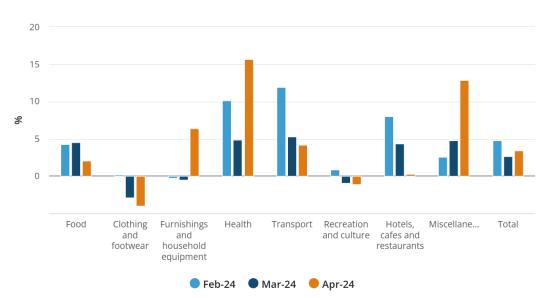


Figure 3 Household spending by category, current price, calendar adjusted²⁸

(A breakdown of health spending to isolate medicine spending is not available)

These people are more likely to be socioeconomically disadvantaged and have multiple chronic conditions requiring multiple long-term medicines, which increases their PBS costs. Not taking medicines can negatively impact the health of these people and could lead to higher government costs due to their worsening health, such as increased likelihood of acute hospitalisations.

²⁷ https://www.abs.gov.au/media-centre/media-releases/household-spending-health-157-past-year

²⁸ https://www.abs.gov.au/statistics/economy/finance/monthly-household-spending-indicator/apr-2024

Cost barriers to PBS medicines

Patient co-payments are an essential policy to ensure the PBS remains sustainable as they contribute to health system financing. Co-payments also address the problem of 'moral hazard'²⁹, which posits that free or low-cost products or services lead to unnecessary or frivolous consumption. Evidence indicates co-payments can reduce both unnecessary and necessary consumption of prescription medicines. Co-payments are considered regressive³⁰, as patient out of pocket costs represent a higher proportion of household income for poorer than for richer people, particularly with low socioeconomic groups more likely to have chronic conditions requiring medication than high socioeconomic groups. Cost pressures for prescription medicine also impact patients' quality of life when other necessities need to be deprioritised to pay for prescriptions.

Strategies used by Australians in response to the financial burden of prescriptions include delaying or deferring filling a prescription, delaying seeing a GP, using a medicine already at home or belonging to someone else, ³¹ seeking cheaper alternatives, or rationing prescriptions. ³²

In 2023, the Senate Community Affairs References Committee 'were told of how people are unable to seek healthcare or pay for medicines due to their lack of resources, leading to acute and long-term health conditions and poor wellbeing'.³³

In November 2024, the Consumers Health Forum of Australia (CHF) expressed 'concern' regarding the Australian Bureau of Statistics (ABS) Patient Experiences survey 'showing one in ten Australians, living in areas of most socio-economic disadvantage, delayed or went without prescription medication when it was needed due to the cost.' CHF stated it had:

been hearing more and more from consumers over the last two years that keeping up with healthcare costs is becoming harder. This is particularly the case for those consumers who live with a, or several chronic conditions.³⁴

²⁹ 'Moral hazard' is an economic term in insurance describing the change in behaviour of the insured. In the context of healthcare, it is taken to mean excessive and unnecessary healthcare resulting from the insured not bearing costs. Joanna Sikora-Alicka, 'Moral Hazard and its Implications on Health Insurance Sector – Overview of the Impact of the Covid-19 Pandemic', *Optimum Economic Studies* (2022)

https://repozytorium.uwb.edu.pl/jspui/bitstream/11320/13041/1/Optimum 1 2022 J Sikora Alicka Moral hazard.pdf ³⁰ The World Health Organization (WHO) notes that out of pocket payments 'tend to be a regressive means of funding health care in all countries', but also that 'they are less regressive in countries where people with low incomes are covered by comprehensive statutory health insurance and are exempt from cost sharing on the grounds of income, age or health status. WHO Regional Office for Europe's Health Evidence Network, What are the equity, efficiency, cost containment and choice implications of private health-care funding in western Europe? (2004) pg. 21. https://www.euro.who.int/ data/assets/pdf file/0003/74694/E83334.pdf

³¹ Doran, 'Patient co-payments and use of prescription medicines', pg. 62.

³² National Seniors Productive Ageing Centre, *Senior Australians and Prescription Medicines: Usage, Sources of Information and Affordability* (2012) pg. 13.

https://nationalseniors.com.au/uploads/201210 PACReport Research PrescriptionMedicines 0.pdf

³³ Community Affairs References Committee, *The extent and nature of poverty in Australia: Final report* (2024) pg. 5. https://parlinfo.aph.gov.au/parlinfo/download/committees/reportsen/RB000208/toc pdf/Theextentandnatureofpovert yinAustralia.pdf

³⁴ Consumers Health Forum of Australia, 'Cost of living still impacting access to healthcare' (2024) https://chf.org.au/media-releases/cost-living-still-impacting-access-healthcare

The Australian Bureau of Statistics (ABS) Patient Experiences survey³⁵ is a Multipurpose Household Survey (MPHS) conducted throughout Australia each financial year by the ABS. It supplements the monthly Labour Force Survey (LFS) and is designed to collect statistics for several small, self-contained topics. While this survey provides an indication of cost barriers to medicine use, it has several limitations which limit its utility and the results should be interpreted with caution.

Limitations include:

- The survey does not collect data on whether the prescriptions patients went without / delayed filling were PBS or private prescriptions. Spending on non-PBS medicines represents the largest category of out-of-pocket spending by Australians by far, accounting for about a third of the total³⁶.
- The survey does not consider the nature or severity of the condition for which the medicine
 was needed. For example, there could be a material difference between someone delaying
 filling a prescription by weeks once or twice a year, compared to someone who did not fill a
 prescription at all. And there would be a material difference between someone delaying
 filling a prescription that improves their quality of life compared to someone who needs life
 saving or sustaining medicine.
- The survey does not collect data on whether people who responded were general or concessional patients. Concessional patients were dispensed 88% of PBS prescriptions in 2023-24³⁷.
- People under 15 are excluded. People under 18 years old were dispensed over 12.5 million prescriptions in 2023-24.
- Data are collected in the context of general practice visits only, and would not include medicines prescribed by specialists, or people who missed out on seeing a general practitioner or specialist due to cost who did not get the chance to be prescribed medication.
- The survey does not canvas other strategies patients may use when concerned about cost, such as shopping around for a cheaper price or (depending on their health condition) rationing their medicines, skipping meals, or forgoing other essential expenditure (e.g. rent/mortgage repayments).
- In the 2023-24 survey data was collected from 26,176 fully responding persons³⁸.

Changes to the survey for future years are possible, however they would only be made at the discretion of the ABS as a part of their usual survey design review processes. The Department of Health, Disability and Ageing engages routinely with the ABS to support review of their health-related surveys. Any change would need to be carefully considered to ensure data is comparable

³⁵ https://www.abs.gov.au/statistics/health/health-services/patient-experiences/latest-release

³⁶ https://www.aihw.gov.au/reports/health-welfare-expenditure/patient-out-pocket-spending-medicare-2016-17/data

³⁷ https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/expenditure-prescriptions-report-1-july-2023-30-june-

 $[\]underline{2024\#:}^{\sim}: text = This\%20 report\%20 details\%20 expenditure\%20 and\%20 prescriptions\%20 information\%20 relating, expenditure\%20\%20\%28 cash\%29\%20 basis\%20 for\%202023-24\%2C\%20 unless\%20 indicated\%20 otherwise.$

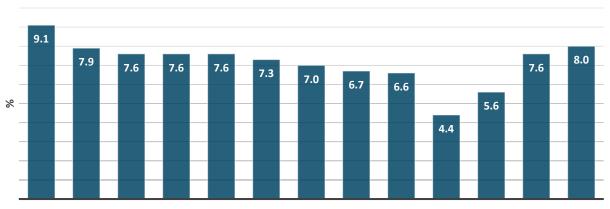
³⁸ https://www.abs.gov.au/methodologies/patient-experiences-methodology/2023-

 $[\]underline{24\#:^\sim:\text{text=This\%20publication\%20contains\%20results\%20from\%20the\%20Patient\%20Experience, throughout\%20Australia\%20from\%20July\%202023\%20to\%20June\%202024.}$

over time, and changes to this survey may not be the most appropriate mechanism to provide the necessary detail.

The 2023-24 Patient Experiences survey indicated the proportion of people aged 15 years and older who delayed or did not get prescription medication due to cost was 8.0%, representing nearly 1.2 million Australians, an increase from 7.6% in 2022-23.

Figure 4 Proportion of Australians Aged 15 Years or Older Reporting Delaying Getting or Did Not Get Prescribed Medication Due to Cost, 2011-12 to 2023-24.³⁹



2011-12 2012-13 2013-14 2014-15 2015-16 2016-17 2017-18 2018-19 2019-20 2020-21 2021-22 2022-23 2022-24

This was most prevalent for those aged 15-24 years than those aged 85 years and over (12.3% compared to 2.4%).

Table 1 Characteristics of Australians Aged 15 Years or Older Reporting Delaying Getting or Did Not Get Prescribed Medication Due to Cost, 2022-23 and 2023-24.

Characteristic		Proportion	
Characteristic	Characteristic		2023-2441
Self-assessed health	Excellent/very good/good	6.4%	6.7%
Sell-assessed fleatill	Fair/poor	15.0%	14.9%
Long-term health	Has LTC	8.4%	9.2%
conditions (LTC)	Does not have LTC	6.1%	5.5%
	Most disadvantage	10.2%	10.9%
to decret veletive endi-	2nd quintile	8.3%	9.0%
Index of relative socio- economic disadvantage	3rd quintile	8.2%	7.5%
conomic disdavantage	4th quintile	6.8%	7.5%
	Least disadvantage	5.4%	5.9%
Remoteness	Major Cities	7.7%	7.9%
Remoteness	Inner Regional	7.4%	8.2%

³⁹ ABS, 'Patient Experiences 2023-24: Table 4'.

https://www.abs.gov.au/statistics/health/health-services/patient-experiences/2022-23

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

⁴⁰ Australian Bureau of Statistics, 'Patient Experiences 2022-23: Table 4' (2023)

⁴¹ Australian Bureau of Statistics, 'Patient Experiences 2023-24: Table 4' (2024)

Chausstavistia		Proportion	
Characteristic		2022-23 ⁴⁰	2023-2441
	Outer Regional/Remote/Very Remote	7.1%	8.2%
Sex	Female	9.4%	9.4%
	Male	6.3%	5.5%

The Australian Patients Association's August 2024 *Australian Healthcare Index*⁴² survey report noted that while government initiatives have reduced the cost of prescription medicines, 'it's clear the cost of prescription medicine remains a challenge for many Australians'. The report noted 'People with health conditions are particularly challenged by cost-of-living pressures and having to change their healthcare behaviour', including skipping buying needed medications (32%).

Nearly two thirds (64%) of the 9,391 people surveyed were taking prescription medication, and of those, 30% said they had gone without medication because of cost concerns in the past six months. This represented an increase from the 22% reporting they had gone without in September 2022, and 27% in June 2023. Nearly three quarters (73%) of people who had gone without prescription medication in the past six months had a health condition, including 72% of the people who went more than a month.⁴³

Over half (58%) of respondents agreed with the statement 'prescription medication is affordable to me', and a third (33%) of respondents in households earning between \$60,000 and \$100,000 disagreed with the statement that prescription medicines were affordable. People living with health conditions were more likely to disagree that prescription medication was affordable to them (30% vs 25% of people without a condition).

The Australian Healthcare Index report also has several limitations which limit its utility and it should be interpreted with caution. Limitations include:

- The survey does not collect data on whether the prescriptions patients were forgoing or found unaffordable were PBS or private prescriptions.
- The survey does not collect data on whether people who responded were general or concessional patients. Concessional patients were dispensed 88% of PBS prescriptions in 2023-24⁴⁴.
- People under 18 are excluded. People under 18 years old were dispensed over 12.5 million prescriptions in 2023-24.
- In the August 2024 survey data was collected from only 9,391 respondents. Respondents were incentivised through the chance to win gift vouchers for responding.

⁴² Australian Patients Association and Healthengine, *Australian Healthcare Index* (2024) pg. 29. https://australianhealthcareindex.com.au/wp-content/uploads/2024/08/AHI Aug 2024 Final.pdf

⁴³ APA and Healthengine, Australian Healthcare Index, pg. 23.

⁴⁴ https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/expenditure-prescriptions-report-1-july-2023-30-june-

 $[\]underline{2024\#:} \text{``:text=This\%20report\%20 details\%20 expenditure\%20 and\%20 prescriptions\%20 information\%20 relating, expenditure\%20\%208 cash\%29\%20 basis\%20 for\%202023-24\%2C\%20 unless\%20 indicated\%20 otherwise.$

While current PBS arrangements provide protections for patients from high prescription costs, barriers may still exist for some patients. The Australian concessional PBS Safety Net is broadly comparable to spending cap levels in many other countries, but the general patient Safety Net threshold is significantly higher than in comparator countries. For example:

- In NZ, where co-payments are NZ\$5 per new prescription (i.e. not for repeats), after a patient pays NZ\$100 (20 prescriptions) they are no longer required to pay co-payments for the rest of the year (noting children aged under 13 years, seniors aged 65 years and over, and Community Services Card holders are exempted from co-payments).⁴⁵
- In England, co-payments are capped through prescription prepayment certificates (PPC), with no co-payments above the cap. PPCs are £32.05 for 3 months and £114.50 for 12 months, where the co-payment is normally £9.90. 46 With a range of co-payment exemptions applying to different groups, almost 90% of prescriptions were dispensed free of charge in England in 2019, with almost 63% dispensed free of charge because the patient was aged 60 years or over. 47
- Co-payments for outpatient prescription medicines were removed for Scotland in 2011,
 Northern Ireland in 2010, and Wales in 2007.⁴⁸
- Since 2019 in the Netherlands, no co-payments are paid after the €250 cap is reached (with a mandatory deductible of €385 for healthcare costs in a year), with health insurers paying the remaining amounts.⁴⁹
- As of 2023, Norway has an annual cap of 3,040 NOK (approximately €260) on co-payments for outpatient prescription drugs on the 'blue' list of treatments (serious illnesses or of risk factors that are likely to cause or intensify serious illness and where there is a need or risk of recurring treatment over a prolonged period of time).⁵⁰

Price elasticity of demand

Prescription medicines are generally considered 'price inelastic', that is, they have low demand sensitivity to price changes.

⁴⁵ Health New Zealand, 'Prescriptions' (2024) https://info.health.nz/conditions-treatments/medicines/prescriptions

⁴⁶ NHS Business Services Authority, 'NHS Prescription Prepayment Certificate (PPC)', (2024)

 $[\]underline{https://www.nhsbsa.nhs.uk/help-nhs-prescription-costs/nhs-prescription-prepayment-certificate-ppc}$

⁴⁷ Department of Health and Social Care, 'Aligning the upper age for NHS prescription charge exemptions with the State Pension age' (2023) <a href="https://www.gov.uk/government/consultations/aligning-the-upper-age-for-nhs-prescription-charge-exemptions-with-the-state-pension-age/aligning-the-upper-age-for-nhs-prescription-charge-exemptions-with-the-state-pension-age

⁴⁸ Nora Cooke O'Dowd, Stephanie Kumpunen and Holly Holder, *Can people afford to pay for health care? New evidence on financial protection in the United Kingdom*, World Health Organization (2018) pg. x.

https://apps.who.int/iris/bitstream/handle/10665/329456/9789289053310-eng.pdf

⁴⁹ Government of the Netherlands, 'Keeping medicines affordable',

https://www.government.nl/topics/medicines/keeping-medicines-affordable

⁵⁰ Apotekforeningen, *Pharmacies and pharmaceuticals in Norway: Key Figures 2023* (2024) pg. 6. https://www.apotek.no/Files/Filer 2014/Engelske sider/Key%20figures%202023.pdf

At an aggregated and general level, international studies estimate elasticity of demand for medicine costs ranging from -0.33 to -0.12.51 A 2009 Australian study analysed PBS demand with co-payment increases (from 1991-92 to 2005-06) found elasticities, varying by Safety Net categories, to be:

- general non-Safety Net: -1.1 to -1.4
- general Safety Net: -1.4.
- concessional non-Safety Net: -0.5 to -0.9.⁵²

This suggests that general patients were more sensitive to the PBS co-payment increases than concessional beneficiaries, but this may be a result of different types of medicines used by each group.

Medicines differ from other consumer goods as patients rely on clinical decision-making to determine the necessity of medicines to improve their health outcomes, and cost is often a lower-order priority for patients, compared to the efficacy and side-effects of medicines. The reliance on clinical advice limits the effectiveness of price signalling⁵³. In addition, the current PBS settings in Australia would largely avoid the over-consumption of medicines.

However, evidence shows that price elasticity can varies with the type of medicine, and the patient group such as the wealthy and healthy vs. the poor and chronically ill^{54,55}. Demand for essential medicines, which are related to serious illnesses, is more inelastic than the demand for less essential medicines⁵⁶.

Price elasticity of demand of the PBS co-payment has not been analysed under this impact analysis. Such research would be possible to conduct, noting that it would be resource intensive to do so and may require external specialist skills (data privacy and secrecy provisions would need to be explored). There may also be gaps in the data constraining its utility, such as whether patients shopped around prior to their purchase, and the overlap with non-cost factors of CRNA (which are not systematically collected).

A potential proxy of price as a factor in patient medicines consumption could be changes in patient demand within a medicine market that has brand competition and/or price premiums. The extent of brand competition/discounting that is occurring, and its influence on consumer behaviours, stratified by essential / less essential medicines and general / concessional patients (as a proxy for

⁵¹ Kai Yeung, et al, 'Price Elasticities of Pharmaceuticals in a Value-Based-Formulary Setting', National Bureau of Economic Research (2016) pg. 4. https://www.nber.org/system/files/working papers/w22308/w22308.pdf

⁵² Kim Sweeny, 'The Demand for PBS Medicine', Centre for Strategic Economic Studies, Working Paper No. 45 (2009) pp. 29-30. https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.372.6151&rep=rep1&type=pdf

⁵³ WHO, What are the equity, efficiency, cost containment and choice implications of private health-care funding, pg. 20;

⁵⁴ Peter Siminski, 'The Price Elasticity of Demand for Pharmaceuticals amongst High Income Older People in Australia: A Natural Experiment', University of Wollongong, Economics Working Paper Series (2008) pp. 38-39. https://ro.uow.edu.au/cgi/viewcontent.cgi?article=1186&context=commwkpapers

⁵⁵ Kim Sweeny, 'The impact of co-payments and safety nets on PBS expenditure', *Australian Health Review* (2009) pp. 228-229. https://www.publish.csiro.au/AH/AH090215

⁵⁶ Cristina Hernandez-Izquierdo, et al, 'The effect of a change in co-payment on prescription drug demand in a National Health System: The case of 15 drug families by price elasticity of demand', *PLoS ONE* (2019) https://doi.org/10.1371/journal.pone.0213403

socioeconomic disadvantage). The Department will explore whether such analysis is feasible in light of other priority work to support the effective delivery of the PBS.

Cost-related non-adherence

The primary negative impact of co-payment unaffordability is cost-related non-adherence (CRNA) of necessary medicines, leading to avoidable health system costs.

In 2022–23, Australia spent an estimated \$252.5 billion on health goods and services – an average of approximately \$9,597 per person. This spending accounted for 9.9% of the gross domestic product (GDP) in Australia.⁵⁷

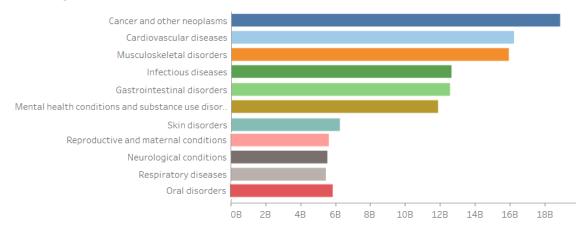


Figure 5 Expenditure by Australian Burden of Disease Groups, 2022-23.58

People with chronic health conditions have an ongoing burden of health care costs. If they do not take their medicines because of cost, their condition may deteriorate. This can impact not only the individual through a change in clinical outcomes, quality of life, and the ability to earn an income, but also on the taxpayers and the broader economy. When people are unwell, they need more health services, including possible hospitalisation or intense services for acute events, and cannot contribute productively to the economy.⁵⁹

In 2024, Australians lost 5.8 million years of healthy life (total burden, Disability Adjusted Life Years/DALY), or 0.2 DALY per person due to living with illness or injury (non-fatal): 54% of total burden or dying prematurely (fatal): 46% of total burden⁶⁰.

In 2022, the 5 disease groups causing the most burden were cancer, mental health conditions & substance use disorders, musculoskeletal conditions, cardiovascular diseases and neurological conditions (Figure 6 Proportion of Total Burden for the Leading Five Diseases Groups, 2022.). Together these

⁵⁷ https://www.aihw.gov.au/reports/health-welfare-expenditure/health-expenditure

⁵⁸ Australian Institute of Health and Welfare, 'Health system spending on disease and injury in Australia 2022–23' (2024) https://www.aihw.gov.au/reports/health-welfare-expenditure/health-system-spending-on-disease-and-injury-aus/

⁵⁹ Department of Health, Disability and Ageing, *Lowering the Costs of Medicines Through Changes to Maximum Dispensing Quantities: Impact Analysis* (2024) pp. 12-13.

https://oia.pmc.gov.au/sites/default/files/posts/2023/05/Impact%20Analysis 3.pdf

⁶⁰ https://www.aihw.gov.au/reports/burden-of-disease/australian-burden-of-disease-study-2024/contents/key-findings

disease groups accounted for around two-thirds (64%) of the total disease burden. These disease groups include mostly chronic, or long-lasting, conditions.

% of total burden 20 16% ■ Fatal ■ Non-fatal 15% 15 13% 12% 10 8% 5 0 Mental/substance Cancer Musculoskeletal Cardiovascular Neurological use Disease group

Figure 6 Proportion of Total Burden for the Leading Five Diseases Groups, 2022.61

PBS usage relating to these diseases is material, comprising 5 of the top 10 medicines by volume in 2023-24⁶², highlighting the importance of medicines in the management for these conditions.

Table 2 Top 50 ATC Level 2 Drug Groups by Highest Total Prescription Volume, 2023-24

Rank	Disease Group	Group	Prescriptions
1	Cardiovascular system	Agents acting on the renin-angiotensin system	39,887,366
2	Nervous system	Psychoanaleptics	38,572,103
3	Cardiovascular system	Lipid modifying agents	38,012,059
7	Multiple indications /diseases	Analgesics	20,263,519
10	Cardiovascular system	Beta blocking agents	9,603,336

PBS expenditure relating to these diseases is also material, comprising 4 of the top 10 diseases by medicine cost to Government in 2023-24.

Table 3 ATC Main Groups Comparison for PBS Subsidised Prescriptions Government Cost, 2023-24

Rank	Disease Group	Cost
1	Antineoplastic and immunomodulating agents (Cancer)	\$7,225,980,407
2	Nervous system	\$1,554,089,294
5	Cardiovascular system	\$1,287,646,771
9	Musculo-skeletal system	\$664,137,896

A 2010 study of seven countries (Australia, NZ, UK, US, Netherlands, Germany and Canada) found

⁶¹ Australian Institute of Health and Welfare, *Australian Burden of Disease Study 2022* (2022) pg. 4. https://www.aihw.gov.au/getmedia/d9ae4bfa-df27-4e3c-9846-ba452bef6ac5/aihw-bod-37.pdf.aspx

⁶² https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/expenditure-prescriptions-report-1-july-2023-30-june-

 $[\]underline{2024\#:^{\sim}:text=This\%20 report\%20 details\%20 expenditure\%20 and\%20 prescriptions\%20 information\%20 relating, expenditure\%20\%208 cash\%29\%20 basis\%20 for\%202023-24\%20 C\%20 unless\%20 indicated\%20 otherwise.$

that cost-related underuse of medicines was least commonly reported in countries with the lowest out of pocket costs (the Netherlands and the UK). In Australia, Canada, NZ, the UK and the US, cost-related underuse was predicted by high out of pocket costs, below average income, and younger age. Countries with reduced co-payments or cost ceilings for low-income patients showed the least disparity in rates of underuse between income groups, with household income predicting the likelihood of underuse due to cost in all countries except Germany and the Netherlands.

While a thorough analysis of links between cost barriers, CRNA and health system costs/burden of disease in relation to the PBS has not been undertaken, it is a reasonable proposition based on the evidence (see

⁶³ Anna Kemp, et al, 'Determinants of self-reported medicine underuse due to cost: A comparison of seven countries', *Journal of Health Services Research & Policy* (2010) https://doi.org/10.1258/jhsrp.2009.009059

Cost barriers to PBS medicines

) that cost barriers are currently contributing to lower medication-CRNA. Evidence also exists to show that lower medication-CRNA leads to higher health system costs⁶⁴ (in addition to poorer patient outcomes⁶⁵).

Medication adherence is complex and multifactorial – addressing cost barriers for patients through a co-payment reduction may only be one response necessary to improve overall adherence. However, given the significant and increasing impact of health costs on Australians' budget⁶⁶ addressing cost barriers through a co-payment reduction is likely to make a meaningful contribution.

Effectiveness of Existing Policies

Recent measures aimed at making PBS medicines more affordable in order to reduce the number of people delaying or not filling their prescriptions, include:

- July 2022 Safety Net threshold reduction
- January 2023 general patient co-payment reduction
- September 2023 commencement of 60-day dispensing (implemented over three stages)
- January 2025 freeze on indexation of the concessional patient co-payment

These measures have collectively provided substantial benefits to patients through paying less for their medicines.

Table 4 Patient savings from affordability measures from 2022

Affordability measure	Prescriptions	Patient savings
2022 Safety Net threshold reduction	71,666,343	\$535,765,814
2023 general patient co-payment reduction	59,937,171	\$758,299,154
2023 60-day dispensing	34,371,235	\$247,204,792
2025 concessional patient co-payment indexation freeze	77,294,784	\$11,215,939
2025 general patient co-payment indexation freeze	12,509,884	\$15,458,394

The long terms impacts of these measures on CRNA rates or other downstream outcomes like health system costs and health and wellbeing, is not yet clear because evaluation has not been conducted.

An external 2025 study on the 2023 co-payment reduction found:

the copayment reduction did not lead to detectable increases in prescription volumes, although it resulted in temporary reductions in inflation-adjusted OOP expenditure for all drugs during the 15 months following the policy. ... Further research is needed to assess

https://www.sciencedirect.com/science/article/pii/S0953620523002339?via%3Dihub;

https://www.tandfonline.com/doi/full/10.1080/08870446.2022.2144923#d1e165;

https://www.ahajournals.org/doi/full/10.1161/STROKEAHA.120.033133

⁶⁴ https://pmc.ncbi.nlm.nih.gov/articles/PMC5780689/; https://www.cdc.gov/pcd/issues/2020/20 0244.htm; https://pubmed.ncbi.nlm.nih.gov/40635744/;

⁶⁵ https://pubmed.ncbi.nlm.nih.gov/40635744/;

⁶⁶ https://www.abs.gov.au/statistics/economy/finance/monthly-household-spending-indicator/apr-2024

the longer-term effects of copayment reductions, particularly their impact on medication adherence and overall healthcare costs. ⁶⁷

The Government does not currently collect CRNA data, nor systematically analyse external CRNA studies, so it is not possible to determine what policy options would have the largest influence on CRNA rates. Evaluation was not required for the January 2023 co-payment reduction, even though that was a larger reduction than this proposal.

Data that could demonstrate the actual/possible cost barriers to medicine usage would be a combination of linked administrative government data, such as (not exhaustive):

- Prescribed vs dispensed medicines (and private vs. PBS scripts)
- Health condition being treated (e.g. acute, chronic, episodic)
- Concessional card status of individuals and family unit (noting this impacts the Safety Net)
- Medicine cost (when prescribed and when dispensed), including change in costs
- Reason for not filling prescription (e.g. cost, patient choice, prescription provided 'in case' of worsening condition, etc.)
- Socioeconomic status (e.g. disability, employment, income, location, other indicators of socio-economic disadvantage, carer, etc.)
- Key demographic indicators (e.g. age, sex, health status, etc.)

While PBS data contains some information on demographic groups, a linked dataset including the above data does not exist. The closest data source would be the Person Level Integrated Data Asset (PLIDA) in which the Department of Health, Disability and Ageing participates. The Department is exploring the utility of PLIDA for PBS-related activities, noting there is likely to still be limitations in data access given legislative barriers in the linking and use of some of the above data items.

⁶⁷ Mohammad Afshar Ali, Firouzeh Noghrehchia and Christine Y. Lua, 'The short-term impact of copayment reductions for government subsidised medicines in Australia', *Expert Review of Pharmacoeconomics & Outcomes Research* (2025) https://doi.org/10.1080/14737167.2025.2451140

2. Why is government action needed?

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

As the current patient co-payments for PBS listed medicines are established under legislation, this legislation would require amendment to change patient financial contributions. The Government is able to develop and introduce potential legislative amendments to the Parliament for consideration.

Affordability for individuals

Pillar 1 of the National Medicines Policy covered in Background is the 'Equitable, timely, safe and reliable access to medicines and medicines-related services, at a cost that individuals and the community can afford'.

It is critical that all Australians can afford the medicines and medicines-related services they need. This is particularly important for people with multiple health conditions taking multiple medicines, people with low incomes, and individuals or families experiencing high out-of-pocket health care costs.

With continued and increasing pressure on household budgets⁶⁸, and multiple sources describing a worsening situation around medication-CRNA (see Question 1), there is a significant flow-on risk to people's health and healthcare costs if cost barriers are not addressed quickly.

Supporting accessible and affordable medicines via patient subsidies falls to the Commonwealth and this is an uncontested space. The PBS co-payment and Safety Net have been well-accepted and legislatively embedded parts of the PBS for decades. While a new 'affordability' could be developed through other non-legislatively based programs, such an approach would need to be tested for constitutional and legal validity, and it would not be possible to implement it and provide the cost-of-living relief quickly enough. The co-payment can be adjusted through a straight-forward legislative amendment with minimal risk or adverse effects; there are no constitutional or other barriers of Government deciding to invest in lowering the co-payment.

From the existing affordability mechanisms (described in Background), the general co-payment provides the highest level of savings for the most patients (5.1 million people) and targets people within this group who are likely have little access to government or other financial supports, such as social welfare payments. It must be noted that a general co-payment reduction would also be available to people within this population group who are not experiencing cost-related barriers to accessing their PBS medicines.

⁶⁸ https://www.abs.gov.au/statistics/economy/finance/monthly-household-spending-indicator/may-2025

Compared to Safety Net changes, a co-payment reduction is superior to assist with cost-of-living pressures as patients will pay less at the counter for each prescription without needing to spend more to access cheaper medicines. Savings will accumulate with every above co-payment prescription filled prior to reaching the threshold, and these savings will exceed the value of any savings foregone on prescriptions that no longer reach the threshold. For patients who still exceed the safety net threshold after the general co-payment reduction, the cost prescriptions that exceed the threshold is unchanged. PBS data shows that less than 1% of general patients utilised the Safety Net in 2023 and 2024.

A co-payment reduction is the best approach to provide fast cost-of-living relief for household spending on healthcare, and to address medication-CRNA. However as previously covered, medication adherence is complex and multifactorial (and the data has its limitations). Addressing cost barriers for patients through a co-payment reduction is likely only one response necessary to improve medication-CRNA. Similarly, relieving cost-of-living pressures through a PBS co-payment reduction that benefits 19% of the population on a subset of their household costs may only provide limited relief in some circumstance⁶⁹.

Controls in PBS legislation related to the prescription and supply of medicines, including restrictions on the use of medicines, would provide some protection against over-consumption of medicines, even for discretionary medicines.

Affordability for the community

Co-payments are a critical part of ensuring the sustainability of the PBS. In 2023-24, 9% of the PBS subsidised prescriptions were financed through patient contributions.

Improving affordability for patients under the PBS generally involves an increase in government expenditure. Reducing the co-payment to \$25 (Option 2) would result in increased government expenditure of \$689.1 million over four years from 2025-26, and \$204.8 million per year ongoing from 2029-30.

While some comparable countries have a much lower co-payment, or no co-payment in some circumstances (see Question 1), replicating this in Australia would bring significant upfront expense to the healthcare budget and taxpayers. This level of investment would come at the expense of priorities such as:

- continued listing of new medicines on the PBS,
- investment in other essential health services, such as bulk billing and public hospitals, and/or
- other government spending priorities across portfolios (e.g. Defence).

The Government has a responsibility to ensure that the PBS is managed in a fiscally responsible and sustainable way, so that the Australian community can continue to be able to access affordable medicines into the future. Should a more material investment be contemplated in future – for instance, to align our general co-payment with comparable countries – more analysis would be

⁶⁹ It is noted that the 2025-26 Budget provided a package of cost-of-living relief investments. https://budget.gov.au/content/01-cost-of-living.htm

required. This would including analysis to determine if the current two-tiered co-payments are sufficiently targeted to those with the highest need and to address the specific population group experience medication-CRNA.

As discussed in Question 1, not addressing medication cost-related nonadherence could have a detrimental impact on the broader health system. This could be through escalating illness, unmanaged illness creating acute episodes, and the spread of disease. This would lead to greater health system costs incurred through the need to treat people in a hospital or another high-cost setting, or for them to access high-cost advanced therapies (such as for later-stage disease). This would also increase Government expenditure and put pressure on other spending priorities.

Ensuring people can access necessary treatments would also enable them to continue going to school and work, which is important for workforce participation and improving economic productivity.

Objectives of Government Intervention

Through the 2025-26 Budget and its 2025 Federal Election campaign, the Australian Government committed to introduce legislative amendments to reduce the general patient co-payment for consideration by the Parliament. As well as implementing the Government's election commitment, this policy option (Option 2) has the primary objective of:

Reducing cost barriers to PBS medicines for general patients.

These patients comprise (along with concessional patients) nearly 1.2 million Australians who delayed or did not fill a prescription because of cost, including disadvantaged groups and/or those with multiple chronic conditions (see Question 1).

Patients would pay less at the counter for each prescription without needing to spend more to access cheaper medicines (under the Safety Net). Savings will accumulate with every above copayment prescription filled prior to reaching the Safety Net threshold (when the co-payment will reduce to the concessional rate).

Objectives and benefits of the co-payment reduction are expected to be:

Objec	tive	Success Factor	Metric
1	Reduce cost barriers to necessary PBS medicines for general patients	Savings for patients at the pharmacy counter.Household spending on healthcare.	↓\$ patient co-payment spending ↓% household healthcare spending
		Patients delaying filling or not filling PBS prescriptions due to cost.	√% patients delaying or not filling their prescription due to cost
2	Reduce downstream health system costs relating to medication-CRNA	 Avoidable hospitalisations from unmanaged conditions. Health and social care utilisation (aged care, disability, social welfare). 	↓% avoidable hospitalisations* ↓% admissions to / utilisation of health and social care*

3	Improve health and wellbeing of general	 Growth in the burden of chronic disease. 	√% growth in burden of chronic disease*
	patients	 Workforce participation. 	个 % workforce participation

^{*}Data parameters to link success to medication-CRNA to be determined

Assumptions and constraints

Assumptions underpinning this analysis and Option 2:

- Reducing the PBS general patient co-payment amount would have a direct impact on medication-CRNA
 - PBS-related prescriptions are represented in cost-barrier and CRNA data sufficiently such that a response under the PBS will impact overall rates.
 - General patients are represented in cost-barrier and CRNA data sufficiently such that a response under the PBS will impact overall rates.
- Reducing the cost of each general patient prescription by \$6.60 would be sufficient to change patient decisions and priorities in the context of other cost of living pressures.

Key constraints on success include:

- Financial pressures on Australians that may continue or worsen.
- Cost barriers to healthcare access more broadly may constrain access to a prescriber.
- Not all medicines patients require are available under the PBS.
- Relieving cost-of-living pressures through a PBS co-payment reduction that benefits 19% of the population on a subset of their household costs may only provide limited relief in isolation.
- Patients' behaviour and choices, especially where decisions to delay or not fill a prescription
 are multifactorial and cannot be solely attributed to medicine costs (e.g. medicine side
 effects, longer-term prognosis, access to a pharmacy, education attainment, perceived need
 for the medicine, mental health or cognitive factors and level of understanding of their
 disease/condition/treatment).

Alternatives to Government Action

Alternatives to addressing this problem are limited as the Australian Government is solely responsible for the administration and management of the PBS, to provide timely, reliable and affordable access to necessary medicines for Australians at a cost the community can afford. Current PBS co-payments are determined under legislation, and to change the cost of the majority of medicines for Australians, action would need to be taken by an entity capable of developing and introducing legislative changes for consideration by the Parliament. The Government takes advice from medical experts, including those on the PBAC, on all medical and medicine matters related to the PBS, and makes the final decision on the implementation and timing of PBAC recommendations.

3. What policy options are you considering?

The two options considered in this Impact Analysis are:

Option 1: Continuation of the current general patient co-payment, which would be \$31.60 plus any relevant indexation amount, as of 1 January 2026 (Status Quo).

Option 2: Reduce the general patient co-payment amount from \$31.60 (July 2025) to \$25 from 1 January 2026, with indexation continuing as per current arrangements from 1 January 2027.

Alternatives for making PBS medicines more affordable were considered, including automating the PBS Safety Net and reducing Safety Net threshold. Alternate levels of co-payment reduction were also modelled to inform the \$25 co-payment amount, including the \$19 co-payment proposed by the Pharmacy Guild of Australia. Government considered the \$25 general patient co-payment reduction to be the best policy given patients would pay less at the pharmacy counter for each prescription without impacting competition in the pharmacy market.

Other factors that contributed towards the formulation of Option 2 included amount of prescriptions historically dispensed that were below and above the new co-payment amount, the impact of the co-payment at various levels to competition in the market, the impact of the co-payment reduction on allowable discounts and incentives, the interaction of the co-payment and the Safety Net, and the impact on the PBS expenditure and revenue.

Through the 2025-26 Budget and its 2025 Federal Election campaign, the Australian Government committed to introduce legislative amendments to reduce the general patient co-payment for consideration by the Parliament.

Option 1 – Status quo

The PBS general patient co-payment amount would be \$31.60 plus any relevant indexation amount, as of 1 January 2026.

Option 2 – Reduce general patient co-payment to \$25.00

From 1 January 2026, the general patient co-payment would be reduced from \$31.60 to \$25.00. The general co-payment would be indexed each year from 2027 in line with the CPI.

This option would:

- Save patients \$784.6 million in total over four years from 2025-26, and \$236.9 million per year ongoing from 2029-30,
- Increase government expenditure of \$689.1 million over four years from 2025-26, and \$204.8 million per year ongoing from 2029-30
- Result in a flow-on cost of an estimated \$95.5 million over 4 years from 2025-26 to pharmaceutical manufacturers with Deeds of Agreement in place, and \$31.6 million per year ongoing from 2029-30.

This option supports the aims of the PBS and National Medicines Policy to ensure all Australians have timely, safe and reliable access to effective, high-quality medicines. It will reduce cost barriers to necessary medicines, particularly for more disadvantaged Australians who are more likely to have multiple chronic conditions requiring multiple medicines and face higher monthly total medicine costs.

This option would initially reduce cost barriers for general patients to access PBS medicines, and over time would:

- Reduce CRNA rates
- Reduce the proportion of patients delaying/not filling PBS prescriptions due to cost
- Reduce unavoidable hospitalisations from unmanaged conditions
- Decrease health and social care (aged care, disability, social welfare) costs
- Slow growth in the burden of chronic disease
- Increase workforce participation

This option builds on existing mechanisms that protect high-volume PBS users from excessive costs, such as the Safety Net.

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

Multi-criteria Analysis

To inform the decision as to which of the options delivers the greatest net benefit, a multi-criteria analysis was conducted along with an estimation of the regulatory cost of each option. This approach supports the comparison of the relative benefits of each option. The chosen option reflects the greatest benefit in terms of the multi criteria analysis score, the increase/decrease in regulatory cost

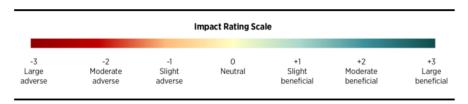
The multi criteria analysis weighs up the extent to which the options work to achieve the Governments objectives:

- Objective 1 Reduce cost barriers to necessary PBS medicines for general patients
- Objective 2 Reduce downstream health system costs relating to medication-CRNA
- Objective 3 Improve health and wellbeing of general patients.

In weighing up the objectives, regard has been given to impacts of each option on the following stakeholders, external to Government, that are likely to be most affected: Patients (consumers), community pharmacies, and pharmaceutical companies with medicines listed on the PBS subject to Deeds of Agreements. The commitment to implement a particular policy approach taken to Australian citizens during an election campaign (Option 2) has also been considered. The Government has made strong assurances it will implement all of its election commitments.

The scale chosen for the assessment is a seven-point scale-3 to +3 (with 0 representing no net change in benefit). The scale shows the anticipated impact of the preferred option on the achievement of the objectives and impact on stakeholder groups relative to the status quo which represents no change to current arrangements. Changes which result in a beneficial impact, or reduce burden, have been rated as positive (green on Figure 7). Changes which increase operating costs or burden have been rated as negative (red on Figure 7). The neutral rating was used to signify minimal impact and that there would be no overall benefit or cost from the option relative to the status quo (yellow on Figure 7).

Figure 7 Seven-point impact rating scale with -3 to -1 indicating an adverse impact, zero indicating no change from the status quo (neutral), and +1 to +3 indicating a beneficial impact.



The nominated values in the impact rating scale are intended to support easy interpretation of the ratings rather than representing a precise scale. Data limitations covered earlier demonstrate that accurate modelling of estimated health system savings resulting from increased PBS consumption would be impractical.

Table 5 Estimate of benefits and likely achievement of each of the options in the context of the three reform objectives outlined in Question 2 using the seven-point impact rating scale

Objective	Option1	Option 2	Comments
Reduce cost barriers to necessary PBS medicines for general patients	-2	+3	 Approx. 5.1 million general patients would pay \$25 per PBS prescription, \$6.60 less per PBS prescription than in 2025. This reduction would remove the cost barrier for some patients and ease it for others. The greatest impact would be for general patients requiring multiple medicines, although they would benefit irrespective of whether they are high-volume PBS users or find PBS medicines to be unaffordable. Women and people of low socioeconomic status are expected to disproportionately benefit. This reduction is expected to disproportionately benefit. This reduction is expected to improve health equity by reducing disparities between high and low socioeconomic groups. People participating in the Closing the Gap PBS Co-payment Program receive PBS benefits at concessional rates or at no cost, so are not impacted by the general patient co-payment reduction. Patients may continue to benefit from pharmacy discretionary discounting, noting this is at the discretion of the pharmacy and the \$1 discount is being phased out. 21% of prescriptions were discounted in 2023-24. Fewer patients would be expected to reach the Safety Net threshold of \$1,694.00 (plus 1 January 2026 indexation amount), as patient would need to pay for approx. 67 above-co-payment prescriptions within the year (up from 53 under Option 1). This represents more than 5 regular medicines each month. However, patients will pay less at the counter for each prescription without needing to spend more to access cheaper medicines. Savings will accumulate with every above co-payment prescription filled prior to reaching the threshold, and these savings will exceed the value of any savings foregone on prescriptions that no longer reach the threshold. For patients who still exceed the value of any savings foregone on prescriptions that no longer reach the threshold. For patients who still exceed the safety net threshol
Reduce downstream health system costs relating to medication-CRNA	-1	+2	 Under Option 1 patients may experience acute events resulting from conditions that aren't well-managed, escalating disease, or poorer quality of life where adherence to prescribed medicines is not optimal. By contrast, Option 2 is expected to show reducing medication-CRNA rates and maintenance of, or improvement in, health and wellbeing.

Objective	Option1	Option 2	Comments	
Improve health and wellbeing of general patients	0	+1	 In 2022, the 5 disease groups causing the most burden were cancer, mental health conditions & substance use disorders, musculoskeletal conditions, cardiovascular diseases and neurological conditions (Figure 6 Proportion of Total Burden for the Leading Five Diseases Groups, 2022.). Together these disease groups accounted for around two-thirds (64%) of the total disease burden. These disease groups include mostly chronic, or long-lasting, conditions. PBS usage relating to these diseases is material, comprising 5 of the top 10 medicines by volume in 2023-24, and PBS expenditure relating to these diseases comprises 4 of the top 10 diseases by medicine cost to Government in 2023-24. It is a reasonable proposition that the burden of disease for the top 5 diseases (and most likely others) is linked to medication-based treatments. And likewise it is a reasonable proposition that patient adherence to the medicine regimen also plays a role. While the evidence to demonstrate these links is lacking, so by subjective assessment a slight benefit is assumed for Option 2, while a neutral impact is assumed for the status quo, Option 1. 	
Indirect benefits for stakeholders	-2	+3	 Under Option 2 Community pharmacies and other approved suppliers would benefit from increased revenue resulting from increased throughput of around 35.9 million PBS prescriptions (this estimate also considers factors separate to Option 2, in line with usual PBS modelling methodology). The pharmacy mark-ups and fees will differ per prescription based on its value and other parameters as outlines in the 8th Community Pharmacy Agreement. Pharmaceutical sponsors will also benefit from increased revenue in the event of increased consumption of PBS medicines of around 35.9 million prescriptions. Option 2 is not expected to have a material impact on pharmacy competition. For PBS medicines priced below the general patient co-payment (under co-payment) pharmacies can set prices and commonly compete on price. There would be a switch of around 3% of prescriptions from under the general co-payment level (based on 2023-24 data) to become 'above' co-payment. These prescriptions could become subsidised by Government with the patient paying the co-payment amount (rather than the full cost of the medicine). 	
Combined score	-5	9		

The Decision Rule applied for the multi-criterion analysis was to identify the option with the highest overall rating across each criterion.

Regulatory Cost Estimate

Table 5 outlines the impact of the options through reduced PBS co-payments. As Option 2 does not change existing business-as-usual practices for any stakeholder, no administrative or compliance costs are imposed, so the Regulatory Burden Measurement Framework was not used to determine impacts. Instead, regulatory impacts were determined in terms of financial savings and costs.

Table 6 Regulatory cost estimate (\$ million) 2025-26 to 2034-35

Option	Individuals	Business	Community organisations	Total change in cost
Option 1 – Status quo	\$0	\$0	\$0	\$0
Option 2 – Reduce the general	\$2,206.0	\$285.1	ćo	\$1,1920.9
patient co-payment to \$25.00	(save)	(cost)	\$0	(save)

Impacts were modelled using the department's Pharmacy Remuneration and Negotiation Consolidated Information System (PhRANCIS):

- PhRANCIS uses prescription volume forecasts and pricing assumptions, based on currently legislated price changes, to estimate PBS expenditure and other budget impacts.
- Patient savings are estimated as the difference between status quo estimated for future years.
- Revenue is estimated using forecasted prescription volumes and rebate percentages applied to PBS items with SPAs and special RSAs, it reflects aggregate revenue forecasts, not total PBS expenditure. Standard RSAs are excluded from revenue estimates as they are designed to mitigate risks and not intended to result in revenue.

Reducing the amount patients would pay for their PBS medicines would result in an increase in government PBS expenditure and a smaller increase in costs for pharmaceutical companies with a Deed of Agreement.

Under Option 1, 316 pharmaceutical companies with medicines listed on the PBS subject to Deeds of Agreements will continue to operate under current rebate arrangements as agreed in their Deed. Revenue paid to the government would continue to be calculated based on existing co-payment amounts from 2026 and actual processed prescriptions.

In contrast, under Option 2:

- 316 pharmaceutical companies with medicines listed on the PBS subject to Deeds of Agreements may pay additional rebates of an estimated total \$95.5 million over 4 years (less than 0.5% variation from 2023-24 PBS revenue).
 - Most of the modelled impact is due to increased rebates payable under special pricing arrangements.
 - Risk-sharing arrangements aim to avoid excess consumption of medicines and so forecasts do not include revenue given financial caps are not expected to be breached.

- The actual value of additional costs is volume dependent and depends on the continuing operation of the Deeds for the duration of this period.
- The impact of general patient co-payment changes on individual companies will vary depending on the specific patient population for the medicine subject to the Deed.
 - Not all 316 sponsors would see a change to their rebate amount, especially when the
 difference between their published and effective price is material and/or the patient
 population codified in their deed is skewed towards concessional patients. In addition,
 the rebate amount is calculated with reference to the prevailing fees and markups at the
 time of listing.
 - The patient population of the PBS (by prescriptions in 2023-24) is 85% concessional patients and 12% general patients (with the balance Repatriation PBS patients). This translates to weighted average co-payment of \$7.76. Under Option 2 the weighted average co-payment reduces to \$7.05.
- Sponsors specifically agree that the Deed continues to operate without modification in the event of a Price Variation (as defined in the deed), which includes variation in the copayment. PBS policy, and therefore Commonwealth Expenditure, changes over time based on the priorities of the Government of the day. Deeds have accommodated regular changes to co-payments (Figure 2) and have not been varied when co-payment amounts change.
- Revenue paid to the government would continue to be calculated based on existing copayment amounts from 2026 and actual processed prescriptions.
- The option would not impact competition for pharmaceutical sponsor as the confidential Deed arrangements will continue to allow companies to list their products on the PBS with a confidential price and remain competitive internationally.

As fewer patients would be expected to reach the Safety Net threshold under Option 2, Government funding for pharmacists to issue Safety Net cards will also reduce.

Table 7 Estimated reductions are (nationally, across 5,977 community pharmacies)

2025-26*	2026-27	2027-28	2028-29	2029-30
-\$ 247,520	-\$ 402,671	-\$ 416,723	-\$ 437,207	-\$ 460,175

^{*2026} only

Greatest Net Benefit

While there is a level of subjectivity to this analysis, overall, Option 2 was considered to have the highest rating across each of the three criteria based on the above seven-point multi-criteria analysis and regulatory impact costings.

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

As Option 2 was announced by the Government as an election commitment during the 2025 Federal Election, significant consultation occurred in the context of the election, which allowed all members of the public and affected stakeholders to consider the proposal and provide feedback to the government about the proposal. Citizens were able to take the proposal into consideration when casting their vote.

Prior to this, major stakeholders advocated for reducing the cost of PBS medicines for patients over the past decade, including individual Australians, consumer advocacy groups, healthcare professional organisations, the pharmaceutical industry, and the community pharmacy sector. Stakeholders have expressed the importance of reducing PBS co-payments to the department at various times in consultation on other policy changes, including the 8th Community Pharmacy Agreement. It is highly likely that all major stakeholders would support Option 2 and would not support a status quo outcome. Prior examples include:

- The Pharmacy Guild of Australia (Guild) recommended the general PBS co-payment be reduced from \$41.30 to \$19.00 in 2021.⁷⁰ In 2023, the Guild recommended the general patient co-payment be reduced from \$30.00 to \$19.00, and the concessional co-payment reduced from \$7.30 to \$6.30.⁷¹ Pharmacists are at the front-line with day-to-day engagement with and support of patients. They are very well positioned to understand the pressures and barriers that patients face.
- In 2022, Better Access Australia recommended reducing the general patient co-payment from \$42.50 to \$20 for those earning less than \$136,000, and freezing co-payment and Safety Net thresholds indexation for five years. Petter Access Australia recommended a further reduction in the \$30.00 co-payment in 2023.
- Medicines Australia, which represents the Australian research-based/innovator industry, supported the co-payment reduction, stating in March 2025 that:

Pharmacy Guild of Australia, 'Submission to the Inquiry into the provision of primary, allied and private health care, aged care and NDIS care services and its impact on the Queensland public health system' (2021) https://documents.parliament.qld.gov.au/com/HEC-B5E1/INDISQ-3CD2/submissions/00000045.pdf

⁷¹ Pharmacy Guild of Australia, 'Pre-Budget 2023-24' (2023) pg. 10. https://consult.treasury.gov.au/pre-budget-submissions/2023-24/view/522

⁷² Better Access Australia, 'Pre-Budget Submission 2022-23' (2022) pg. 4. https://treasury.gov.au/sites/default/files/2022-03/258735 better access australia.pdf

⁷³ Better Access Australia, 'Pre-Budget Submission 2023-24' (2024) https://consult.treasury.gov.au/pre-budget-submissions/2023-24/view/709

The government's announcement of a reduction in the PBS co-pay today is an important measure to ensure patients do not interrupt their treatment and can continue their life changing and lifesaving medicines.⁷⁴

Medicines Australia and certain individual pharmaceutical companies raised concerns with department in relation increased rebates with the 2023 \$30 and 2026 \$25 co-payment reductions. They asserted that funding for measures is partly funded through the medicines industry through Deed revenue arrangements and instead should be fully funded by the government.

Given the views of stakeholders about a co-payment reduction are so well understood and have been so thoroughly represented over a long period of time and were the focus on extensive public consultation during the 2025 Federal election campaign, the department did not undertake further and separate consultation on Option 2.

In addition, the department has access to data needed to assess the impact on all stakeholders from this change, and to determine what magnitude of change would be most favourable (highest copayment reduction and lowest risks to factors such as market dynamics).

⁷⁴ Medicines Australia, 'Patient access to medicines strengthened with PBS co-payment reduction' (2025) https://www.medicinesaustralia.com.au/media-release/patient-access-to-medicines-strengthened-with-pbs-co-payment-reduction/

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

Preferred option

Implementing Options 2 is preferred over the status quo, because it will generate the greatest benefit to Australian and health outcomes, as outlined in this analysis.

Implementation

Implementing Option 2 will require the Parliament to consider and make amendments to the Act to change the PBS general co-payment amounts. This consideration by the Parliament is expected to be completed by late 2025, and if the proposed reforms are supported through legislative amendment, this will enable commencement from 1 January 2026.

As changes to the PBS co-payment amounts are a business-as-usual practice for all stakeholders, including pharmacies and pharmaceutical sponsors, and Services Australia (delivery partner for ICT system), implementation activities and risks are negligible. No implementation risk management is required.

Due to controls that exist in PBS legislation related to the prescription and supply of medicines, including restrictions on the use of medicines to ensure safety and cost-effectiveness, there is a low risk that the co-payment reduction would lead to over-consumption of medicines, even discretionary medicines.

Given the co-payment reduction is expected to have negligible impact on pharmacy competition, and pharmacies can continue to provide discretionary discounts to patients, no pro-active mitigation is required. Competition in the market will continue to be monitored under existing business-as-usual PBS operations.

The primary implementation risk is not having legislative amendments in place for the commencement. To address this risk, the legislative amendments will be tabled in Parliament in July 2025.

Communications

Updates will be made to the PBS and Services Australia websites outlining changes to the PBS copayment arrangements.

The department is exploring the creation of a public communications campaign to manage changes to PBS for patients, pharmacies, and other stakeholders. Using several media channels, the communications campaign would inform patients (as the primary audience) of the reduced copayments with the intent to improve price awareness to overcome cost barriers. The campaign would provide clear and factual information about the PBS changes and expected benefits to patients and encourage uptake of essential prescribed PBS medicines.

Any materials developed would be tailored to culturally and linguistically diverse patients. Historically, the Department has sought advice from a specialist organisation to adapt and translate resources, website content and other materials for culturally and linguistically diverse patients. Specialist First Nations communication advice would also be sought to ensure appropriate strategies and communication materials are implemented for First Nations people.

Campaign documentation would be developed by the Department following budget approval. Subject to this approval, the communications campaign would commence from early 2026.

The department must comply with the *Australian Government Guidelines on Information and Advertising Campaigns* (Guidelines). The Independent Communications Committee (ICC) considers campaigns and provides advice to the departmental Secretary/Chief Executive on all advertising campaigns valued at more than \$250,000 or where requested to do so by the departmental Secretary/Chief Executive. Under the Guidelines, the ICC will consider the proposed communications campaign for the selected option, and provide a report to the department's Secretary on compliance with the following Guideline Principles:

Principle 1: Relevant to government responsibilities

Principle 2: Presented in an objective, fair and accessible manner

Principle 3: Objective and not directed at promoting party political interests

Principle 4: Justified and undertaken in an efficient, effective and relevant manner. 75

In addition, the Government Communications Subcommittee (GCS) of Cabinet provides oversight and coordination of government advertising campaigns. For all options, ICC and GCS review would be sought in early-mid 2025.

⁷⁵ Australian Government, *Australian Government Guidelines on Information and Advertising Campaigns* (2022) https://www.finance.gov.au/sites/default/files/2022-12/Australian-Government-Guidelines-on-Information-Advertising-Campaigns-by-non-corporate-Commonwealth-entities.pdf

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

The department will develop an evaluation plan in accordance with government best practice during the implementation phase in mid-2025 and conduct an evaluation in 2028. An evaluation report will be published, and the department will consult with stakeholders on its findings to inform future policy decisions.

Evaluation Plan

Stage 1: Planning and Budgeting

Purpose: To evaluate whether reducing the general patient co-payment improves affordability, access, and health outcomes, while maintaining system sustainability and assessing potential impacts on the pharmaceutical industry and pharmacy competition.

Objectives:

- Assess improvements in affordability and access for patients.
- Evaluate changes in health outcomes and service utilisation.
- Monitor patient behaviour (e.g. cost-related non-adherence).
- Identify unintended consequences or emerging needs.
- Assess impacts on:
 - o Viability and profitability of pharmaceutical companies, especially Australian-based.
 - Attractiveness of the Australian market for medicine manufacturers.
 - o Price paid by the Commonwealth for PBS-listed medicines.
 - Range of products marketed and PBS-listed.
- Monitor pharmacy competition, especially around discretionary discounting.
- Inform future policy decisions, funding allocations, and industry engagement strategies.

Evaluation Questions:

- 1. Has access to PBS medicines improved for general patients?
- 2. What is the impact on medicine affordability and adherence?
- 3. Are there measurable changes in health outcomes or continuity of care?
- 4. What are the financial and operational impacts on the pharmaceutical industry?
- 5. Has the policy affected the range or availability of PBS-listed products?
- 6. Is there evidence of changes in pharmacy competition due to discounting?

Scope and Approach:

- Mixed-methods evaluation using both process and outcome evaluations.
- Use of existing administrative datasets (e.g. PBS, ABS).
- Ethical and culturally appropriate data handling.
- Evaluation to be conducted internally with potential for external review.

- Industry impact analysis using financial data, stakeholder engagement, and market trend assessments.
- Consumer engagement to capture the potential real-world impacts on Australians in terms of medicine affordability.

Responsible Teams: Program implementation, PBS data analytics, Consumer Evidence and Engagement and Departmental Executive.

Stage 2: Measuring and Assessing

Objective	Success Factor	Metric	
Reduce cost barriers to necessary PBS medicines	Savings for patients at the pharmacy counter	↓\$ patient co-payment spending	
for general patients	Household spending on healthcare	√% household healthcare spending	
	Patients delaying filling or not filling PBS prescriptions due to cost	√% patients delaying or not filling their prescription due to cost	
Reduce downstream health system costs	Avoidable hospitalisations from unmanaged conditions	↓% avoidable hospitalisations*	
relating to medication- CRNA	Health and social care utilisation (aged care, disability, social welfare)	\downarrow % admissions to / utilisation of health and social care*	
Improve health and wellbeing of general patients	Growth in the burden of chronic disease Workforce participation	↓% growth in burden of chronic disease*↑% workforce participation	
Maintain system	Administrative burden		
sustainability	Overuse of services	Stable or justified	
	Changes in PBS spending		
Protect pharmaceutical	Market exits (in Australia and globally)	\downarrow or \rightarrow (no material change)	
industry viability	Investment in / product launches in Australia (new listings)	\uparrow or \rightarrow (no material change)	
	PBS listed items	\uparrow or \rightarrow (no material change)	
	Discretionary discounting and pricing behavior	Stable or justified	

Data Sources:

- PBS claims data
- ABS health surveys
- Services Australia administrative data⁷⁶
- Australian Institute of Health and Welfare data
- Industry financial reports and market data
- Stakeholder feedback (GPs, patients, peak bodies)
- PLIDA and other linked datasets (subject to legislative constraints)
- Departmental patient sentiment surveys / tracking (responses to communications campaign)

⁷⁶ When a PBS/RPBS medicine is dispensed, the administering pharmacy or hospital automatically provides Services Australia with data pertaining to the prescription dispensed, identity of the patient, prescribing doctor, and supplying pharmacy, including the co-payments paid for the prescription.

Data Analysis:

- Comparative analysis of pre- and post-policy implementation trends.
- Stratification by age, sex, location, socioeconomic status.
- Secure data environments and privacy-compliant processes.
- Industry impact modelling (e.g. profitability, market share)

Stakeholder Engagement:

- Drug Utilisation Sub Committee (DUSC) of PBAC, which routinely assesses estimates on projected usage and financial cost for medicines
- Innovator pharmaceutical sector
- Generic manufacturers
- Consumers
- Pharmacy peak bodies
- Australian Bureau of Statistics
- Industry impact modelling (e.g. profitability, market share)
- Findings shared via:
 - o Policy papers
 - Stakeholder forums
 - Feedback loops to inform future decisions.

Stage 3: Reporting and Accountability

Reporting:

- Interim findings to be reviewed within 18 months of implementation.
- Final report to be completed within 30 months.
- Reports will include:
 - Visualisations
 - Policy recommendations
 - o Industry impact assessments
 - o Implications for future co-payment and pricing policies.

Governance:

- Senior Responsible Officer oversees evaluation.
- Department Executive decides on publication and future policy directions.

Use of Evaluation Findings:

- Inform future PBS pricing and co-payment policies
- Guide funding allocations and sustainability measures
- Support strategic engagement with industry to maintain market viability
- Shape regulatory and pricing frameworks to balance affordability and innovation

Timeline Overview:

Task	Responsible	Timing
Evaluation plan creation	Program implementation team	Q1 2026
Decision to begin evaluation	Senior Officer	Q2 2026
Engagement with ABS to determine scope of data	Program implementation team/ PBS data analytics team	Q2 2026
Data collection & analysis	Program implementation team/ PBS data analytics team	Q1 2027 - onwards
Interim findings	Senior Officer	Q4 2027
Stakeholder consultation	Program team	Q4 2027
Final report	Program implementation team	Q2 2028
Publication decision	Department Executive	By Q3 2028