



IMPACT ANALYSIS

LOWERING THE COSTS OF MEDICINES THROUGH CHANGES TO MAXIMUM DISPENSING QUANTITIES

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Executive Summary

This proposal will enable consumers to have an increased maximum dispensed quantity (MDQ) of certain Pharmaceutical Benefits Scheme (PBS) medicines, used for many common and chronic diseases as recommended by the independent Pharmaceutical Benefits Advisory Committee (PBAC).

There are three options for consideration:

- i. Make no change to MDQ of one month's supply;
- ii. Increase the MDQ to two months' supply; or
- iii. Increase the MDQ to three months' supply.

The Impact Analysis contained in this document was prepared in line with the *Australian Government Guide to Policy Impact Analysis*¹ to inform consideration of the proposal in the 2023-24 Budget.

Financial estimates in this Impact Analysis assume that Option 2 or Option 3 would be implemented on a single date in 2023-24.

The Hon Mark Butler MP, Minister for Health and Aged Care, announced the Government's decision to implement this proposal on 26 April 2023.² The Minister announced the Government's decision to implement this policy in three stages, with the first operating from 1 September 2023, the second from March 2024 and the third stage from 1 September 2024.³

An increase in MDQ for certain medicines treating chronic conditions will improve access to and affordability of PBS medicines and build on the recent PBS General Patient Co-Payment reduction to \$30 on 1 January 2023. An increase to the MDQ will mean that consumers with chronic, stable medical conditions will need to make less visits to a pharmacy to fill their prescriptions for some common PBS medicines. This will result in reduced 'out of pocket costs' for both concessional and general patients and provide added convenience for many people.

For example, under the **two month** maximum dispensing quantity option:

- i. Concessional beneficiaries (non-Safety Net) currently pay \$14.60 for two months' supply for medicines requiring a monthly prescription (two co-payments of \$7.30). If this proposal is accepted they will only pay \$7.30 for two months' supply of the same medicines. For a patient who needs 12 months' supply of medicine every year and does not reach the PBS concessional Safety Net, after the MDQ changes they will save up to \$43.80 per year per medicine.
- ii. General beneficiaries (non-Safety Net) currently pay up to \$30 per prescription for their PBS medicines. Some medicines are priced below the general PBS co-payment, however for those medicines that require 12 prescriptions per year and where the dispensed price of the medicine exceeds \$30, general beneficiaries could save up to \$180 per year per medicine.

¹ <https://oia.pmc.gov.au/sites/default/files/2023-02/oia-impact-analysis-guide-nov-22.pdf>

² <https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/cheaper-medicines-to-ease-cost-of-living?language=en>

³ <https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/minister-for-health-and-aged-care-press-conference-26-april-2023?language=en>

This proposal, if adopted by clinicians and consumers, will reduce the volume of PBS dispensing by pharmacies. Pharmacy owners will receive significantly less PBS income due to the decrease in the volume of dispensing related remuneration resulting from the proposed PBS changes. This includes less dispensing payments from the Government and fewer co-payments by patients. However, pharmacy remuneration for all other medicines and from other sources (e.g. commercial sales) will continue.

The impact on specific pharmacies will vary depending on the location of the pharmacy and its operating model. The Government's decision to implement this proposal in three stages may lessen the immediate financial impact on individual pharmacies and allow time for businesses to adjust to changes in revenue. The estimated average impact per pharmacy in the first year of implementation based on the Government's decision to implement this proposal in three stages may be up to \$49,000 reduction in remuneration derived from Government paid PBS fees, which is estimated to be a reduction of approximately 6% of the baseline remuneration of community pharmacy Government paid PBS fees (estimated to be \$775,000 in the first year). For the two month option, the estimated average impact per pharmacy in the fourth year following implementation may be up to \$158,000 reduction in remuneration derived from Government paid PBS fees, which is estimated to be a reduction of approximately 18% of the baseline remuneration of community pharmacy Government paid PBS fees (estimated to be \$867,000 in the fourth year). For the three month option, the estimated average impact per pharmacy in the fourth year following implementation may be up to \$210,000 reduction in Government remuneration, which is estimated to be a reduction of 24% of the baseline remuneration of community pharmacy fees (estimated to be \$867,000 in the fourth year). PBS revenue is only one of the revenue sources for community pharmacies, but is the focus of the financial analysis presented.

This proposal supports consumers to access medicines at lower prices, addressing cost of living pressures. In total, it is estimated that patients who are prescribed prescriptions that allow 2 months' supply per dispense will save around \$540 million in PBS patient contributions in 2026-27, and approximately \$1.8 billion between 2023-24 and 2026-27. For the 3 month option, the total estimated save to patients is \$740 million in PBS patient contributions in 2026-27, and approximately \$2.5 billion between 2023-24 and 2026-27. These financial estimates assume a single implementation date of all MDQ changes in 2023-24 and the Government's decision to implement this proposal in three stages may lessen the immediate savings to patients. Once fully implemented, some patients using MDQ medicines (approximately 1.8 million per year) may avoid visits to a general practitioner (GP) or other prescriber solely for the purpose of obtaining repeat prescriptions for medicines covered under the proposal.

It will also provide savings to Government to reinvest in other priorities by reducing dispensing related remuneration paid to pharmacy owners, which will help to keep the costs of the PBS sustainable.

The Government intends to reinvest savings from the proposal to support the development of new, and expansion of existing programs and services by community pharmacy. This will also help to practically expand the scope of practice for community pharmacists, as well as supporting more clinical services for patients in pharmacy. This includes proposals that seek to increase funding to pharmacy programs over the term of the Seventh Community Pharmacy Agreement (7CPA), fund community pharmacies for the administration of vaccines under the National Immunisation Program (NIP) and provide additional support to remote and regional pharmacies.

Background

1.1 The PBS

The PBS is a national, Government-funded scheme that subsidises the cost of a wide range of medicines for all Australians to help them afford effective treatments. The PBS lists all the medicinal products available under the scheme and explains the conditions for which they can be subsidised.⁴

The PBS is a key program supporting delivery of the Government's [National Medicines Policy](#) (NMP)⁵ which aims to “focus on achieving positive health results that matter to people and their communities and make sure all Australians have timely, safe and reliable access to effective, high-quality medicines.” The PBS is available to all Australian residents who hold a current Medicare card. Overseas visitors from countries with which Australia has a Reciprocal Health Care Agreement are also eligible to access the Scheme.

The operation of the PBS is established by the *National Health Act 1953* (the Act). This Act establishes the responsibility of the statutory independent expert advisory committee, the PBAC, in its primary role of recommending, to the Minister for Health and Aged Care, which medicines and medicinal preparations should be subsidised under the PBS and which vaccines are subsidised under the National Immunisation Program.

Under the PBS, the Australian Government subsidises the cost of medicine for most medical conditions. Most PBS medicines are dispensed by community pharmacies and used by patients at home. These are known as ‘General Schedule’ or ‘section 85’ medicines because **section 85** of the Act establishes the ability for the Minister for Health and Aged Care to list medicines on the PBS and for the Commonwealth to supply the pharmaceutical benefit.

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

The Government pays pharmacists to procure, supply and dispense all PBS medicines to consumers throughout Australia. A dispensing fee paid to pharmacists is set by the Government and forms part of the total price paid for a PBS medicine. The dispensing fee is adjusted on the first of July each year.

The cost of a medicine is negotiated between the government and the supplier of the medicine. The agreed price becomes the basis of the dispensed price of the medicine. Pharmacists purchase PBS-listed medicines from the wholesaler or supplier. The price of the medicine to pharmacy includes the wholesaler's mark-up. The Dispensed Price for Maximum Quantity (DPMQ) listed on the PBS website is

⁴ https://www.health.gov.au/sites/default/files/documents/2019/10/department-of-health-annual-report-2018-19_0.pdf

⁵ [National Medicines Policy | Australian Government Department of Health and Aged Care](#)

the price for dispensing the maximum quantity of a product under a given prescribing rule. The DPMQ incorporates the approved ex-manufacturer price (AEMP) and all relevant dispensing fees and mark-ups (wholesale and pharmacy). Pharmacists claim the difference between the dispensed price and the patient co-payment contribution from Services Australia.

The PBS Schedule lists all of the medicines available to be prescribed and dispensed to patients at a Government-subsidised price. The Schedule is part of the wider PBS managed by the Department of Health and Aged Care and administered by Services Australia. This schedule is published online and updated on a monthly basis. The online searchable version contains:

- all of the medicines listed on the PBS
- the form, strength, quantity of medicines supplied and number of prescription repeats allowed
- information on the conditions of use for the prescribing of PBS medicines
- detailed consumer information for medicines that have been prescribed by their doctor or dentist
- what consumers can expect to pay for medicines.

1.2 The role of the PBAC

The PBAC is an independent expert body appointed by the Australian Government. Members include doctors, health professionals, health economists and consumer representatives. When recommending a medicine for listing, the PBAC takes into account the medical conditions for which the medicine was registered for use in Australia, its clinical effectiveness, safety and cost-effectiveness ('value for money') compared with other treatments.

A new medicine cannot be listed on the PBS unless the PBAC makes a positive recommendation for its listing. Under **section 101** the Act, the PBAC must take into account both the cost and clinical effectiveness of the medicine when compared with other treatments for the same condition. The PBAC recommends maximum quantities and repeats of a pharmaceutical benefit or pharmaceutical item.

Under Part VII, Division 1, of the Act, the maximum quantity (MQ) is the 'quantity or number of units of that pharmaceutical benefit or pharmaceutical item that is determined by the Minister, under paragraph 85A(2)(a), to be the maximum quantity, or the maximum number of units, of that pharmaceutical benefit or pharmaceutical item that may, in one prescription, be directed to be supplied on any one occasion.'⁶

1.3 Which medicines does the government subsidise?

The Government subsidises medicines that are necessary to maintain the health of the community in a way that is cost-effective. This is achieved by carefully assessing the therapeutic benefits and costs of medicines, including comparisons with other treatments where appropriate. If a medicine is found to be acceptably cost-effective, then government negotiates its price with the supplier.

⁶ <https://www.legislation.gov.au/Details/C2020C00062>

The PBAC⁷ has a broad statutory function under the Act, to advise the Minister for Health and Aged Care on any matters concerning the operation of the PBS, which includes making further recommendations regarding the safety, effectiveness, and cost-effectiveness of medicines after they have been listed.

The PBAC is responsible for evaluating the clinical and cost-effectiveness of medicines in order to make recommendations relating to listing on the PBS. Recommendations for new listings are informed by evidence of a medicine's clinical effectiveness (how well it works), safety, and cost-effectiveness ('value for money') compared with other treatments for a particular group of patients with a health condition, including but not limited to other medicines to treat those patients for that condition.

The PBS covers life-saving and life-changing medicines across a broad range of conditions, from asthma and arthritis to diabetes and cancer. The PBAC takes into account if the medicine will affect the use of other healthcare and related resources (e.g. reduced GP visits, shorter or no hospitalisation, improved quality of life etc.). A cost-effective and clinically-effective PBS medicine may reduce expenditure in other areas of the healthcare system.

1.4 What are the current patient fees and charges?

To help meet the cost of the scheme, patients pay a 'co-payment' for PBS medicines and the Government pays the remainder of the listed cost. Many PBS medicines cost significantly more than the co-payment amount. From 1 January 2023, the general beneficiary patient co-payment was reduced from \$42.50 to \$30.00. Also from 1 January 2023, medicines for general patients with a dispensed price between \$30.00 and \$45.60 may be discounted to any price (including a price below \$30.00). Patients may pay up to \$30.00 for most PBS medicines or \$7.30 if they are a concession card holder. Co-payment amounts are adjusted in line with indexation on 1 January each year.

Since 1 January 2016, pharmacists may choose to discount the PBS patient co-payment by up to \$1.00. This is not mandatory and it is the pharmacist's choice whether or not to provide a discount.

1.5 The PBS Safety Net supports patients with high medicine costs

The PBS Safety Net protects patients and their families requiring a large number of PBS or Repatriation PBS (RPBS) medicines. The Safety Net threshold is reached by accumulating eligible patient contributions for PBS or RPBS prescriptions supplied through community pharmacies and private hospitals and for out-patient medication supplied by public hospitals.

The scheme requires pharmacists, on request by patients, to record the supply of PBS and RPBS items on prescription record forms. When a patient and their family reaches the Safety Net threshold within a calendar year, they qualify to receive PBS or RPBS items at a cheaper price or free of charge for the remainder of that calendar year. Any applicable special patient contributions, brand premiums or therapeutic group premiums must still be met by the patient.

As at 1 January 2023, the Safety Net thresholds were \$262.80 (for concession card holders) and \$1,563.50 (for all general beneficiary patients). After reaching the Safety Net threshold, general patients

⁷ [Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee, Version 5.0 \(pbs.gov.au\)](https://www.pbs.gov.au/healthcare/medicines/pbs/pbs-guidelines-for-preparing-a-submission-to-the-pharmaceutical-benefits-advisory-committee-version-5.0)

pay for subsequent PBS prescriptions at the concessional co-payment rate and concession card holders are not charged the PBS co-payment for medicines dispensed over the remainder of that calendar year.

1.6 Seventh Community Pharmacy Agreement (7CPA)⁸

The Seventh Community Pharmacy Agreement (7CPA) is an agreement between the Commonwealth of Australia, the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia. It supports consumer access to PBS subsidised medicines through community pharmacies across Australia.

The 7CPA has an overall funding envelope of \$18.35 billion, comprising:

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

The 7CPA commenced 1 July 2020 and will be in place until 30 June 2025.

The 7CPA⁹ recognises that community pharmacy is an integral part of the Australian health care system through its role in supporting the PBS, and can provide a broader range of clinical services to the community beyond medicine dispensing services. To further support Australians' access to PBS and RPBS medicines and appropriately remunerating community pharmacy for services, the signatories to the agreement are committed to:

1. Ensuring Australians have access to patient focused, outcome oriented professional pharmacy services and programs that support the safe and quality use of medicines
2. Predictable remuneration for community pharmacies to support their viability and allow for an efficient and effective network of approved pharmacies and pharmacists across Australia, while ensuring the proper use of public resources
3. Ensuring that out of pocket expenses for PBS and pharmacy programs are transparent and appropriate
4. Maintaining a co-operative relationship between the signatories and a broader more inclusive set of key stakeholders, to ensure that Australian patients receive the best possible outcomes from the PBS and associated community pharmacy programs.

The delivery of professional pharmacy programs is forecast to expend more than the agreed \$1.2 billion. This proposal is part of a package of measures seeking to re-invest savings realised by implementation of changes in maximum dispensing quantities for medicines, as recommended by the PBAC, back into the community pharmacy to support the delivery of new and expanded services by pharmacy. This includes

⁹ [7CPA-signed-Agreement.pdf \(pbs.gov.au\)](#)

proposals that seek to increase funding for pharmacy programs over the term of the 7CPA, fund the administration of vaccines under the National Immunisation Program (NIP) by pharmacies and provide additional support to remote and regional pharmacies.

1.7 Current PBS fees, co-payment and safety net arrangements

The co-payment arrangements help to ensure that medicines remain affordable and are valued by patients, improving sustainability of the PBS. The full cost of medicines is shown on pbs.gov.au. The full cost is also shown on the dispensing label. The following fees, patient contributions and Safety Net thresholds apply as at 1 January 2023 are included, where applicable, in prices published in the Schedule.

Table 1.1 PBS Fees, Patient Contributions and Safety Net Thresholds 1
January 2023

Dispensing Fees:	Ready-prepared	\$7.82
	Dangerous drug fee	\$4.84
	Extemporaneously-prepared	\$9.86
	Allowable additional patient charge*	\$3.29
Administration, Handling and Infrastructure Fee (AHI Fee):	Tier One: For a Listed Brand with a Price to Pharmacists for Maximum Quantity less than \$100	\$4.32 per dispense of Maximum Quantity
	Tier Two: For a Listed Brand with a Price to Pharmacists for Maximum Quantity from \$100 and up to and including \$2,000	Tier One AHI Fee plus 5% of the amount by which the Price to Pharmacists for Maximum Quantity exceeds \$100, per dispense of Maximum Quantity
	Tier Three: For a Listed Brand with a Price to Pharmacists for Maximum Quantity over \$2,000	Tier One AHI Fee and \$95 per dispense of Maximum Quantity.
Additional Fees (for Safety Net prices):	Ready-prepared	\$1.31
	Extemporaneously-prepared	\$1.68
Wholesale Mark-Up:	When the Ex-Manufacturer Price is up to and including \$5.50	\$0.41 per dispense
	Where the Ex-Manufacturer Price is over \$5.50 and up to and including \$720	7.52 per cent of the Ex-Manufacturer Price per dispense
	Where the Ex-Manufacturer Price is over \$720	\$54.14 per dispense
Patient Co-payments:	General (maximum)	\$30.00
	Concessional	\$7.30
Safety Net Thresholds:	General	\$1,563.50
	Concessional	\$262.80
Safety Net Card Issue Fee:		\$11.42

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

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

1.8 PBAC Recommendation

In August 2018, the PBAC considered a proposal for doctors to be given the choice to prescribe larger medicine quantities (two months' supply) for some patients who have chronic stable medical conditions, for particular medicines listed on the PBS. The PBAC outcome statement related to this proposal was

published by the Department of Health.¹⁰ The Government did not proceed with changes to the quantities for PBS medicines at that time.

In December 2022, the PBAC considered and provided advice on a proposal that would improve access to PBS medicines for patients with stable, chronic medical conditions by providing prescribers the choice to prescribe an increased dispensed quantity for selected PBS medicines; two months' or three months' supply instead of the current one month's supply at each dispensing.

The PBAC considered a list of medicines from the General Schedule (section 85) listed for use in chronic conditions for suitability for the proposal. Based on an assessment of clinical safety and ongoing cost-effectiveness, the PBAC recommended that some 300 plus medicines were acceptable for listing with increased maximum quantities. The PBAC also agreed on a criterion and standard restriction wording for all medicines included in this proposal, to ensure the higher maximum dispensed quantity items are only prescribed to patients whose condition is stable. The PBS items with the increased maximum dispensed quantities would be in addition to the medicine's corresponding current PBS items that provide one month's supply and five repeats. Prescriptions for smaller quantities could still be prescribed for patients as clinically appropriate, avoiding medicine wastage and supporting closer clinical monitoring of patients where required.

The PBAC considered that this proposal would allow clinicians to exercise greater choice and provide patients both financial and convenience benefits through choosing to prescribe the increased maximum quantity if clinically appropriate. The PBAC also considered that allowing two or three months' supply per dispensing was safe for the list of recommended medicines and that the implementation of increased maximum quantities allowing two or three months' supply was a decision for Government. The PBAC did not express a preference for either option and considered that allowing two or three months' supply per dispensing was safe for the list of recommended medicines.

The list of medicines recommended by the PBAC as suitable for increased maximum dispensed quantities includes medicines for asthma, cardiovascular disease, chronic obstructive pulmonary disease (COPD), constipation, chronic renal failure, Crohn disease, depression, diabetes, epilepsy, eye drops for glaucoma and dry eyes, gout, heart failure, high cholesterol, hormonal replacement and modulation therapy, hypertension, osteoporosis, Parkinson disease and ulcerative colitis. There are some medicines for conditions that require frequent clinical monitoring or dose titration that are not considered by PBAC as safe and suitable for dispensing in higher quantities.

The PBAC outcome statement from December 2022¹¹ and list of medicines recommended by the PBAC for an increase in MDQ¹² was published at pbs.gov.au.

¹⁰ <http://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2018-08/Outcome-Statement-August-2018-Increased-MDQ.pdf>

¹¹ <https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2022-12/december-2022-pbac-web-outcomes-other-matters.pdf>

¹² <https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2022-12/Increased-Dispensing-Quantities-List-of-Medicines.pdf>

Impact Analysis

1. What is the problem this proposal will solve?

Cost of living pressures

The PBS, funded by the Australian Government, subsidises the cost of most prescription medicines for all eligible Australians. Consumers pay a PBS co-payment to the pharmacist for each dispensing of their medicine. Following changes introduced on 1 January 2023, the PBS co-payment is \$7.30 for concessional patients and \$30 for general patients per dispensing.

Researchers^{13 14} and consumers have raised concerns regarding the monthly cost of PBS medicines. In November 2019, the Consumers Health Forum of Australia stated that reducing the requirement for consumers on routine medication to visit a pharmacy each month would improve accessibility, convenience and affordability for consumers.¹⁵

Research suggests that 1 in 5 Australians aged 18-64 find prescription medicines to be unaffordable and that more than 900,000 Australians delayed or did not fill their prescriptions due to cost in 2019-2020.¹⁶ The Australian Bureau of Statistics Report, *Patient Experiences (2021-22)*¹⁷ found over 771,000 Australians did not fill their prescriptions or delayed having their prescribed medicine dispensed due to cost. The proportion of people who delayed or did not get prescription medication when needed due to cost increased to 5.6% in 2021-22, from 4.4% in 2020-21. In addition, those Australians with a long-term health condition were more likely to delay or not get prescription medication dispensed due to cost than those without a long term health condition (6.4% compared to 3.8%).

The Australian Patient's Association (APA) 2022 Australian Healthcare Index Report¹⁸ showed that of people taking prescription medicine, 24% disagreed when asked whether medicine was affordable to them, increased from 19% in the previous survey (October 2021)¹⁹. The medicines affordability issue is a concern for both the non-concessional (largely under 65) population and the older population, with 29% of people aged 50 to 64 disagreeing that medicines were affordable, along with 13% of people aged 65 or over.

People with chronic health conditions have an ongoing burden of health care costs. If they do not take their medicines because they cannot afford to fill a prescription their condition is likely to deteriorate, which impacts not only the individual through a change in clinical outcomes, quality of life, and the

¹³ <https://www.yourlifechoices.com.au/health/news/paying-too-much-for-meds>

¹⁴ [Not so universal: How to reduce out-of-pocket healthcare payments - Grattan Institute](#)

¹⁵ <https://chf.org.au/media-releases/open-pharmacy-agreement-give-consumers-better-deal>

¹⁶ <https://www.patients.org.au/affordable-medicines-now/>

¹⁷ Australian Bureau of Statistics (2021-22), *Patient Experiences*, ABS Website, accessed 18 January 2023.

¹⁸ <https://australianhealthcareindex.com.au/australian-healthcare-index-june-2022-report/>

¹⁹ [Australian-Healthcare-Index-Report-2-October-2021.pdf \(australianhealthcareindex.com.au\)](#)

ability to earn an income, but also on the taxpayers and the broader economy. When people are unwell they need more health services and cannot contribute productively to the economy.

Access and convenience

Patients in the community, who have chronic medical conditions and are prescribed medicines listed on the PBS, obtain their medication through community pharmacies. A valid PBS prescription for a chronic condition usually provides six months of medication supply, dispensed monthly by the pharmacist. This means patients with a chronic stable condition are required to visit their doctor every six months to obtain a new prescription.

While there are some exemptions to reduce the burden on consumers to return to the pharmacy to access prescription medicines, these are limited in scope. Under current PBS regulations, original prescriptions and the maximum number of repeat supplies allowed of pharmaceutical benefits can only be supplied at the one time if a prescriber is satisfied that the maximum dispensing quantity is insufficient for the patient's treatment; the patient has a chronic illness and lives in a remote area where access to PBS supplies is limited; or the patient would suffer great hardship trying to get the pharmaceutical benefit on separate occasions. A co-payment is still required for each original and repeat supply of the PBS medicine. For example, a single month's supply of simvastatin 10 mg tablets would cost a concessional patient one co-payment of \$7.30. If the patient filled five repeat prescriptions on separate occasions, six months' supply of the medicine would cost $6 \times \$7.30 = \43.80 . If the pharmacy applied the optional \$1 discount at each dispensing, the cost reduces to \$37.80. If the same patient satisfies the conditions above and receives the same medicine and has the original prescription and five repeats dispensed at the one time, the cost would still be $6 \times \$7.30 = \43.80 or \$37.80 if the \$1 discount per dispensing is applied.

Through the MBS Review²⁰, the CHF raised consumer concerns about patient access to repeat prescriptions for continuing medications and that the current PBS restrictions limited flexibility with regard to prescriptions for medicines to treat many chronic conditions.

Sustainability of the PBS

The cost of the PBS is expected to continue to grow, and this will put increased pressure on the health budget.²¹ Total PBS Government expense for the supply of medicines for the 2021-22 financial year was \$14.7 billion (excluding revenue from rebates paid to Government for medicines with special pricing arrangements and/or risk sharing arrangements), compared with \$13.8 billion for the previous year. This is an increase of 6.7%.²² To ensure the ongoing sustainability of the PBS, both the medicines subsidised

²⁰ <https://www1.health.gov.au/internet/main/publishing.nsf/Content/MBSR-about>
<https://www1.health.gov.au/internet/main/publishing.nsf/Content/MBSR-about>

²¹ [https://www1.health.gov.au/internet/main/publishing.nsf/Content/4BC52286D3009386CA257BF000209AD5/\\$File/Impact%20of%20PBS%20Reform%20Report%203.pdf](https://www1.health.gov.au/internet/main/publishing.nsf/Content/4BC52286D3009386CA257BF000209AD5/$File/Impact%20of%20PBS%20Reform%20Report%203.pdf)

²² <https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions-report-1-july-2021-to-30-june-2022#:~:text=Summary%20of%20Pharmaceutical%20Benefits%20Scheme%202021-22%20Total%20Pharmaceutical,compared%20with%20%2413.8%20billion%20for%20the%20previous%20year>

and the programs through which medicines are supplied and accessed are reviewed regularly by Government.

2. Why is government action needed?

The central pillars of the refreshed 2022 National Medicines Policy²³ are:

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

The intended outcome of the first pillar is that medicines and medicine 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.

Ensuring equity of access to medicines and medicine-related services for all Australians involves considering effectiveness, safety, affordability and the health, social and economic benefits. The Australian Government provides subsidised access to medicines and vaccines through the PBS, the RPBS and the NIP. Medicines are also accessed through public and private hospitals, clinical trials, compassionate access programs, or privately purchased (including non-prescription medicines). This is supported by access arrangements between federal, state and territory governments for certain technologies.

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. 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.

The Government is committed to:

- Convenient and affordable access for consumers to PBS medicines for many chronic conditions
- Lower healthcare costs for consumers and Government without compromising patient safety
- Improvements to the PBS to provide more choice for doctors and consumers
- Consistently implementing the recommendations of the independent PBAC
- Maintaining the sustainability of the PBS.

There are some constraints to the Government taking action. There is a risk that the proposal will raise concerns for pharmacy stakeholders. However, based on recent public representations and discussion, the proposal has support from prescribers and consumers and will reduce the out of pocket costs of PBS medicines for millions of Australians. A comprehensive public education campaign will be required to

²³ [National Medicines Policy | Australian Government Department of Health and Aged Care](#)

clearly explain how the changes will work for patients and how these PBS changes will interact with other PBS policy and legislation, including the PBS safety net. This will also explain the expanded role for pharmacies in the delivery of clinical services and programs, which will also support the viability of this important part of the health care system. Consumers with chronic conditions will need to be informed and encouraged to raise this opportunity to be considered for a prescription for an increased MDQ for their medicine with their prescriber.

Prescribing and dispensing software vendors will be consulted prior to implementation of the proposal to ensure the new arrangements will be reflected in the software update from the start date. Inclusion of the large volume of PBS Schedule changes (new PBS items and amended PBS items) into one monthly software update may mean that other PBS changes may not be progressed in that specific PBS listing month. This will allow the high volume of changes to be made and to ensure that no errors are created in the PBS data where other changes may affect the same medicines as the MDQ changes.

3. What policy options are you considering?

The Government is considering the advice provided by the PBAC to increase the maximum dispensed quantities of certain PBS medicines.

The options being considered in this Impact Analysis are:

- Option 1 - maintain the status quo
- Option 2 - Implement MDQ changes for medicines - 2 months' supply
- Option 3 - Implement MDQ changes for medicines - 3 months' supply

Option 1: Status quo

- In general, one month's supply of PBS medicine per dispense by a pharmacist.
- Each prescription provides six months' supply of medicine, there will be six dispense events per prescription.

Stakeholder roles and responsibilities

Consumers

- Under the status quo, there is no change to existing process. Consumers will visit a pharmacy each month to have their prescription dispensed and visit the GP or other prescriber for a new prescription every six months, depending on the medicines they take and the stability of their medical conditions.
- Reduced access to pharmacy programs to cut program expenditure on programs such as Dose Administration Aids and Medication Management Reviews to the level agreed in the 7CPA.

Pharmacies

- Pharmaceutical benefits are mainly supplied by approved pharmacists, who are approved to dispense medicines from particular pharmacy premises. All approved pharmacists are subject to certain conditions under the Act related to pricing, record keeping, supply and advertising. The roles of the prescriber and dispensing pharmacist are complementary and these health care professionals work together to improve patient outcomes.²⁴
- Under the status quo, there is no change to existing process. Pharmacies will receive a dispensing fee (\$7.82)²⁵ plus an Administration, Handling and Infrastructure (AHI) fee per dispense of a month's supply of medicine. The AHI fee ranges from Tier One: \$4.32 to Tier Three: \$4.32 + \$95 per dispense of Maximum Quantity (the tier dependent on the price of the medicine to pharmacy).²⁶
- There is no expected change in prescription volumes dispensed.

²⁴ [Collaboration between doctors and pharmacists in the community - Australian Prescriber \(nps.org.au\)](https://www.nps.org.au)

²⁵ As at 1 January 2023 pbs.gov.au

- No redirection of dispensing cost savings to support expanded scope of practice and the delivery of new and expanded services and programs in community pharmacy. The current level of programs being delivered under the 7CPA will need to be reduced to fit within the \$1.2 billion envelope available under the 7CPA.

Prescribers²⁷

- Pharmaceutical benefits can only be prescribed by doctors, dentists, optometrists, midwives and nurse practitioners who are approved under the Act. The roles of the prescriber and dispensing pharmacist are complementary and these health care professionals work together to improve patient outcomes.
- Under the status quo, there is no change to existing process. Prescribers can prescribe one month's supply per dispensing and up to six months' supply of a medicine per prescription (in general) for medicines to treat chronic stable conditions.

Government

- There is no change to existing process and no change in PBS or 7CPA expenditure. The Government continues to pay pharmacies handling fees for monthly dispensing of PBS medicines. No change to the numbers of consumers reaching the PBS Safety Net threshold in a calendar year.

Software vendors

- There is no change to the business as usual monthly prescribing and dispensing software updates.

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- There is no change to business as usual monthly listing processes. Changes and additions to the PBS can be progressed as usual.

²⁷ The PBS items subject to the MDQ changes can be prescribed by medical practitioners, nurse practitioners and optometrists, the permitted prescriber for each PBS item is noted in the PBS Schedule.

Medicine sponsors

- A sponsor²⁸ is a person or company who does one or more of the following: exports therapeutic goods (medicines) from Australia, imports therapeutic goods into Australia, manufactures therapeutic goods for supply in Australia or elsewhere, arranges for another party to import, export or manufacture therapeutic goods. The sponsor is responsible for applying to the Therapeutic Goods Administration (TGA) to have their medicine included on the Australian Register of Therapeutic Goods (ARTG) and for making an application to the PBAC to list their medicine on the PBS.
- Sponsors will not be required to change Australian on shore stock for certain PBS medicines.

Pharmacy wholesalers²⁹

- Pharmaceutical wholesalers maintain distribution facilities for medicines and are the link between sponsors of medicines and community pharmacies where the medicines are dispensed to patients.
- Pharmaceutical wholesalers will not be required to change current stock levels or experience reductions in remuneration through legislated wholesaler mark ups.

Option 2: Implement MDQ changes for medicines – 2 months' supply

- If a patient's condition is stable and suitable for the increased MDQ, a prescriber may provide a prescription for 2 months' supply of some PBS medicines per dispense.
- Each prescription with the increased MDQ will supply approximately 12 months' medicine - as there will be six dispense events, each providing 2 months' of medicine supply per prescription.
- New and amended items will be listed on the PBS schedule with an increased MDQ sufficient to last the patient approximately 2 months, and in most cases the prescription will have the same number of repeats i.e. one original and 5 repeats.
- It is necessary to list new PBS items as the PBAC has explicitly recommended that the increased MDQ listing for medicines in the proposal are in addition to, and not a replacement of, the current one month PBS listing for these medicines, allowing for appropriate decision making by prescribers.
- These changes to the PBS will be made to the Schedule at the same time.
- The savings to Government made possible by Option 2 will support programs and services provided to patients under the 7CPA, including higher volume of existing programs, higher payments under the Regional Pharmacy Maintenance Allowance and new programs, including funding for administration of NIP vaccines to eligible patients in community pharmacies.

²⁸ [Role of the sponsor | Therapeutic Goods Administration \(TGA\)](#)

²⁹ www.npsa.org.au/#:~:text=The%20Pharmaceutical%20Wholesale%20Industry%20is%20a%20vital%20part,%20pharmacies%20where%20they%20are%20dispensed%20to%20patients

Stakeholders and roles and responsibilities

Consumers

- Consumers will experience lower costs for accessing medicines they need to manage their chronic conditions. This is because patients will pay fewer co-payments (approximately half for each medicine with increased MDQ) or if the medicine is priced under the co-payment, one dispensing and AHI fee for two months' supply instead of one months' supply as currently occurs under Option 1.
- Some consumers would need to visit a pharmacy every second month instead of each month to have their prescription dispensed and may reduce their GP visits depending on the medicines they take and the stability of their medical conditions.
- Consumers who only take medicines subject to the MDQ changes may only be required to visit their GP once a year for a new prescription instead of the current situation where they need to obtain a new prescription every 6 months.
- Consumers will continue to benefit from services and programs provided by community pharmacies, including services such as Dose Administration Aids, Medication Reviews and vaccine administration under the NIP, due to re-investment of some of the Government save into these Programs.

Pharmacies

- Pharmacies will receive a dispensing fee (\$7.82)³⁰ plus an Administration, Handling and Infrastructure (AHI) fee per dispense of two months' supply of a PBS medicine (Range: Tier One: \$4.32 to Tier Three: \$4.32 + \$95 per dispense of the maximum quantity). The tier is dependent on the price of the medicine to pharmacy.³¹
- Business as usual monthly dispensing software update will incorporate new and amended PBS medicine items.
- Increased level of stocks may need to be held to fulfil increased maximum quantity prescriptions.
- Pharmacies may experience temporary changes to cash flow to purchase an increased stock level during the initial implementation phase.
- Pharmacies will be able to offer more professional services under Government-funded programs, including more patient services under existing 7CPA programs and under new programs which will expand the scope of practice of pharmacists in community pharmacy, for the administration of NIP vaccines.

Prescribers

- Prescribers will have the option to consider prescribing higher quantities of all medicines included in the proposal to patients with chronic, stable conditions if clinically appropriate.

³⁰ As at 1 January 2023 pbs.gov.au

³¹ As at 1 January 2023 pbs.gov.au

- Prescribers will still have discretion to prescribe one month's supply per dispensing and up to six months' supply of a medicine per prescription, avoiding medicine wastage and supporting closer clinical monitoring of patients where required.
- Many patients with chronic conditions that require ongoing medication will no longer be required to attend a doctor's consultation at least twice a year to obtain their prescriptions for these medicines. Prescribers may have the opportunity to use these appointments to spend time with patients on more complex health issues and consultations, rather than writing repeat prescriptions for medicines to treat patients with chronic stable conditions.

Software vendors

- Software vendors will have a high volume of new and amended PBS items to add to prescribing and dispensing software through business as usual processes.
- Other changes to the PBS Schedule may not be able to be progressed in that specific PBS listing month to allow the high volume of changes to be made and to ensure that no errors are created in the PBS data where other changes may affect the same medicines as the MDQ changes.

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- A high volume of new and amended PBS items will be added to business systems and databases.
- The volume of PBS items to be added/amended exceeds usual monthly changes. Other changes to the PBS Schedule may not be able to be progressed in that specific PBS listing month to allow the high volume of changes to be made and to ensure that no errors are created in the PBS data where other changes may affect the same medicines as the MDQ changes.

Medicine sponsors

- Initially, medicine sponsors may be required to increase Australian onshore stock in the short term for certain PBS medicines. Total amount of medicine supplied will not increase overall.

Pharmacy wholesalers

- Wholesalers may be required to temporarily increase stock levels depending on the uptake of the changes in the initial implementation phase.
- Remuneration for wholesalers may be reduced because of the way remuneration is calculated. Wholesaler mark-ups are derived according to legislative requirements. Wholesale mark-ups apply in three tiers, a flat fee for tiers one and three (low and high cost medicines) and a percentage mark-up for tier two. The changes will only impact medicines with prices that fall in tier one or tier three either for the single quantity item or the increased maximum dispensed quantity item.

Option 3: Implement MDQ changes for medicines – 3 months' supply

- If a patient's condition is stable and suitable for the increased MDQ item, a prescriber may provide a prescription that allows 3 months' supply of some PBS medicines per dispense.

- Each prescription will provide approximately 12 months' supply of medicine because there will be a maximum of four dispense events i.e. an original and 3 repeats per prescription. A PBS prescription is only valid for 12 months³² from the time it is written. Therefore, if the 3 month MDQ option is implemented the number of repeats per prescription will need to be adjusted to allow a maximum of 12 months' supply of medication.
- New and amended items will be listed on the PBS schedule with an increased MDQ sufficient to last the patient approximately 3 months, and a reduced number of repeats to provide sufficient medication for a maximum of 12 months.
- It is necessary to list new PBS items as the PBAC has explicitly recommended that the increased MDQ listing for medicines in the proposal are in addition to, and not a replacement of, the current one month PBS listing for these medicines, allowing for appropriate decision making by prescribers.
- These changes to the PBS will all be made to the Schedule at the same time.
- The savings to Government made possible by Option 3 will support programs and services provided to patients under the 7CPA, including higher volume of existing programs, higher payments under the Regional Pharmacy Maintenance Allowance and new programs, including funding for administration of NIP vaccines to eligible patients in community pharmacies.

³² [National Health \(Pharmaceutical Benefits\) Regulations 2017 \(legislation.gov.au\)](#) Part 5 – Prescriptions and supply 44, 2 (b)

Stakeholders and roles and responsibilities

Consumers

- Some consumers would need to visit a pharmacy every third month instead of each month to have their prescription dispensed and may reduce their GP visits to once per twelve months depending on the medicines they take and the stability of their medical conditions.
- Consumers will pay a co-payment for every three months' quantity of medicine versus for every one month's quantity of medicine under the status quo.
- Consumers who only take medicines subject to the MDQ changes may only be required to visit their GP once a year for a prescription, if all their medicine prescriptions can be renewed at the same time.

Pharmacies

- Pharmacies will receive a dispensing fee (\$7.82)³³ plus an Administration, Handling and Infrastructure (AHI) fee per dispense of three months' supply of medicine (Range: Tier One: \$4.32 to Tier Three: \$4.32 + \$95 per dispense of maximum quantity). The tier is dependent on the price of the medicine to pharmacy³⁴.

All other stakeholder roles and responsibilities as for Option 2.

³³ As at 1 January 2023 pbs.gov.au

³⁴ As at 1 January 2023 pbs.gov.au

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

Option 1: Status quo

Access to all PBS medicines and the current quantity of medicines dispensed would remain unchanged. This would not address the cost barriers to access to medicines detailed above under 'Cost of Living pressures'. For the majority of PBS listed medicines used to treat chronic conditions, patients are required to consult their prescriber every six months to obtain a new prescription and to return to a pharmacy each month to have one month's supply of medication dispensed. The exceptions are:

- some commonly prescribed medicines are currently available on the PBS with increased maximum quantities that require higher than normal doses. For medicines such as corticosteroid creams for eczema and antibiotics for indications with a specific treatment course, there is no requirement to obtain prior Services Australia approval
- the oral contraceptive pill (unrestricted listing, four months' supply per dispensing with two repeats)
- medicines available under the 12 month repeat measure (implemented in 2008-09) which allows prescriptions for one month's supply and 11 repeats to be issued by a prescriber, a total of 12 months' supply.

Pharmacists would continue to receive a dispensing fee (\$7.82)³⁵ plus an Administration, Handling and Infrastructure (AHI) fee (Range: Tier One: \$4.32 to Tier Three: \$4.32 + \$95 per dispense of Maximum Quantity, tier dependent on the price of the medicine to pharmacy)³⁶ for each dispense. There will be six dispense events per prescription or twelve dispense events per year (once the patient has obtained a second prescription).

Option 2: Implement MDQ changes for medicines – 2 months' supply

When fully implemented, the proposed changes could benefit a significant proportion of the base number of 9.6 million patients (derived in the next section) when their prescriber's assessment is that the patient's chronic condition is stable and suitable for the higher maximum dispensed quantity item. These patients could benefit from a reduction in the number of individual PBS co-payments they would have to make for medicines included in the MDQ proposal, and visits to the doctor and pharmacy may be reduced. Implementing the two month supply option will provide less savings to Government and consumers than Option 3, but the financial impact on pharmacies would also be less than for Option 3.

Consumers

Implementation of Option 2 will provide ongoing financial and convenience benefits for consumers. It will facilitate equitable access for consumers to higher quantities of PBS medicines, pending individual assessment of a patient's suitability by their prescriber.

³⁵ As at 1 January 2023 pbs.gov.au

³⁶ As at 1 January 2023 pbs.gov.au

This option will reduce the financial barrier to accessing medicines experienced by low income, elderly and other vulnerable patients³⁷, and patients taking multiple medications. The risk of patients missing medication dosages at the end of each month when their prescription runs out may be reduced.

Some patients will effectively reduce their out of pocket medicines costs by up to half for Option 2. For example:

- Concessional ordinary (non-Safety Net) patients currently pay \$14.60 for two months' supply for medicines requiring a monthly prescription (two co-payments of \$7.30), under this proposal they will only pay \$7.30. For a patient who needs 12 months' supply every year and is in a family that does not reach the PBS concessional Safety Net after the MDQ changes that is a saving of \$43.80 per year for each medicine included in the proposal.
- General ordinary (non-Safety Net) patients currently pay up to \$30 per prescription for their PBS medicines. Some medicines are priced below the general PBS co-payment, however for those medicines that require 12 prescriptions per year and where the dispensed price of the medicine exceeds \$30, general patients could save up to \$180 per year.

In total, it is estimated that patients who are prescribed prescriptions that allow two months' supply per dispense will save around \$540 million in PBS patient contributions in 2026-27, and approximately \$1.8 billion between 2023-24 and 2026-27. Once fully implemented, this represents a significant reduction in out of pocket costs for patients accessing PBS medicines. The extent to which an individual patient is impacted is dependent on a number of contributing factors which include:

- The prescriber assessing the patient's chronic condition as stable and suitable for the higher maximum dispensed quantity item
- The number of medicines affected by the proposal that a patient is prescribed
- Whether patient has a concession card for accessing PBS medicines
- Whether the patient, as part of a family or individually, reaches the PBS Safety Net
- For a general patient, the cost of the individual medicine the patient is prescribed, and how this price is impacted by the increased quantity listing.

The complex interaction of these factors has been considered in the detailed financial modelling and analysis supporting the proposal. To account for this complexity, the financial impact of the proposal has been modelled as the reduction in prescriptions for the single quantity items, the uptake of the increased quantity items and the patient types accessing these prescriptions.

The detailed prescription volume and pricing forecasts that underpin the model account for:

- The range of medicines impacted by the proposal
- The rate of uptake of prescribing the increased quantity items
- Whether the prescription is for a concessional or general patient
- Whether the prescription is for a patient who individually, or as part of a family, has reached the PBS Safety Net

³⁷ Kemp Anna, Preen David B., Glover John, Semmens James, Roughead Elizabeth E. (2011) How much do we spend on prescription medicines? Out-of-pocket costs for patients in Australia and other OECD countries. *Australian Health Review* 35, 341-349. <https://doi.org/10.1071/AH10906> .
<https://doi.org/10.1071/AH10906>

- The setting in which the prescription is dispensed (across community pharmacy, private or public hospital)
- Assumptions about changes in the future price of medicines
- Changes in the policy environment and projected indexation of patient co-payments, the PBS Safety Net threshold, fees and mark-ups for wholesalers and pharmacies.
- Special Pricing Arrangements and Risk Sharing Arrangements with sponsors for certain medicines.

Considering each of these factors, the estimated financial impact on consumers takes into account the financial benefit to the patient each time a dispensing of two prescriptions for one month's supply are replaced by a single prescription for two months' supply.

Consumers taking only those medicines subject to the MDQ changes will visit a pharmacy every second month instead of each month to have their prescription dispensed and may reduce their doctor visits. Consumers may reach their applicable PBS Safety Net threshold later in the calendar year and co-payment costs may be spread more evenly across the calendar year, rather than concentrated in the first half of the calendar year. For medicines included in the MDQ proposal, consumers would pay a co-payment every second month to receive 12 months' supply in total of medicine per prescription. For the same medicine under the status quo, consumers pay a co-payment each month, or twelve per year. Comparing the two month option to the status quo, three co-payments would be required in the first six months of the year rather than six co-payments.

The base number of patients eligible for the proposal was derived from PBS data. Around 9.6 million consumers received two or more dispensing of medicines included in the proposal in 2022.³⁸ The rate that consumers are likely to take up this proposal is assumed to be gradual, increasing from a 45% aggregate reduction in the volume of eligible prescriptions for the single month's quantity items in Year 1, 58% in Year 2, 63% in Year 3 to 63% in Year 4. The ceiling uptake rate of 63% is based on a study of a previous rollout of increased MDQ for some items. The consumer take up rate is assumed to be the same under Option 2 and Option 3 as the same group of PBS patients will have been assessed by their prescriber to have chronic medical conditions that are stable and therefore suitable for increased MDQ items.

Once the MDQ changes are fully implemented, it is expected that the aggregate impact on eligible prescription volumes for these patients across all MDQ items will be a 63% reduction in prescriptions for the single month's quantity item. Because two prescriptions for the single quantity item will become one prescription for the double quantity item, half the amount of prescriptions that were reduced for the single quantity items will be taken up for the double quantity items. Patients whose prescriptions are included in this reduction in aggregate prescription volumes could benefit through reduced numbers of individual PBS co-payments.

The subgroup of patients who receive **only** PBS medicines with increased MDQ items (approximately 1.89 million patients by 2026-27) have been estimated to save 35 minutes (consultation and travel time) attending a GP clinic annually and 90 minutes (6 visits x 15 minutes) attending the pharmacy annually.

³⁸ Department of Health and Aged Care April 2023

Consumers who live in rural or regional areas or who find it difficult to visit a pharmacy each month may experience added convenience.

The following table shows the Direct Regulatory Impact savings for consumers if the MDQ is increased to two months' supply for medicines included in the proposal.

It is estimated around 1.8 million patients will benefit in 2023-24, with total reduction in regulatory burden of approximately \$135 million. This increases to more than 1.89 million patients, with more than \$141 million in reduced regulatory burden by 2026-27.

The following method and assumptions were used:

1. The base number of patients eligible was derived from PBS data. Around 9.6 million patients received two or more dispensing's of the PBS medicines in the list found suitable by the PBAC for increased MDQs in 2022. Of these, a subset of 1.77 million patients were only dispensed the increased MDQ medicines (and no other PBS medicines), therefore may benefit from fewer visits to the pharmacy and prescriber (GP).
2. At a population level, the assumed growth rate of PBS patient numbers per year is 1.6% based on ABS population projections. In 2023-24, it is assumed that the number of unique patients that will be prescribed more than one prescription for an MDQ item (but no other PBS subsidised medicines) will be 1.8 million.
3. Number of person minutes saved is GP visit x 1.8 million patients x 35 minutes (GP visit³⁹ + travel time of 15 minutes) + 6 pharmacy visits x 1.8 million patients x 15 minutes (pharmacy visit only, travel not included⁴⁰).
4. Consumer/person time saved per pharmacy visit does not include travel time. GP offices and pharmacies may be co-located.
5. The default value for an individual's leisure time is estimated at \$36⁴¹ per hour.
6. The estimated regulatory impact of the save is: (consumer/person minutes saved x \$36), divided by 60.
7. The estimated regulatory impact assumes a single implementation date in 2023-24.

³⁹ Level B consultation Item 23 Medical Benefits Schedule www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=23

⁴⁰ Estimated by consultation with Department of Health and Aged Care practicing community pharmacists

⁴¹ 2022 Regulatory Burden Measurement Framework | The Office of Impact Analysis (pmc.gov.au)

Table 4.1: Direct Regulatory Impact savings for consumers by increasing MDQ - two months' supply

Number of times per year each patient affected				
2023-24	2024-25	2025-26	2026-27	TOTAL
GP visits saved per year				
1	1	1	1	
Pharmacy visits saved per year				
6	6	6	6	
Number of patients affected				
1,800,000	1,830,000	1,860,000	1,890,000	
Number of person minutes saved (annual)				
2023-24	2024-25	2025-26	2026-27	
225,000,000	228,750,000	232,500,000	236,250,000	
Estimated Regulatory Impact value of patient save (annual)				
2023-24	2024-25	2025-26	2026-27	Total
\$135,000,000	\$137,250,000	\$139,500,000	\$141,750,000	\$553,500,000

Source: 2023 Impact analysis costing- MDQ 2 month OIA22IA-03771

*Average annual patient save: \$138,375,000

Pharmacies

The community pharmacy sector will be significantly impacted by this proposal. Owners of over 5,900 pharmacies will receive less dispensing income due to the decrease in the volume of dispensing and related remuneration resulting from the proposed changes. Some pharmacies may experience temporary changes to cash flow to purchase an increased stock level during the initial implementation phase, however this is likely to be mitigated by favourable terms of trade extended by suppliers to pharmacies, which is an established practice.

There will be little time for business owners to transition to other income sources, although the Government is providing increasing financial support for pharmacies to deliver patient services, including new vaccinations to eligible patients under the NIP to provide opportunities to ameliorate the business impact and diversify into other public-funded health programs.

The full impact of the reduction in dispensing volumes will not occur immediately. Financial modelling assumes that consumer uptake of the proposal will increase from a 45% aggregate reduction in the volume of eligible prescriptions for the single month's quantity items to a 63% aggregate reduction in the volume of eligible prescriptions for the single month's quantity items over the next four years. Many consumers will still have valid prescriptions for their medicines at the time of implementation and may only choose to seek a prescription for an increased quantity of medicine at their next scheduled doctor's appointment. The availability of medical appointments will also limit the numbers of patients seeking a

consultation for the sole purpose of obtaining a prescription for an increased quantity of their PBS medicines at the time of implementation.

Pharmacies will be paid one fee for dispensing two months' supply of a medicine on the one occasion, rather than one fee paid on two separate occasions for dispensing a month's supply of medicine over two separate months. The proposed changes will financially impact on pharmacy businesses, as pharmacists will receive less dispensing and handling fee income due to the decrease in dispensing volumes and associated fees received from Government.

The impact on specific pharmacies will vary depending on the location of the pharmacy and its operating model. For the two month option, the estimated average impact per pharmacy in the fourth year following implementation may be up to \$158,000 reduction in remuneration, which is estimated to be a reduction of approximately 18% of the baseline remuneration of community pharmacy fees (estimated to be \$867,000 in the fourth year). PBS revenue is only one of the revenue sources for community pharmacies, and other sources of income are not captured in this analysis. The impact by individual pharmacy will vary considerably according to its operating model and factors such as:

- Dispensing volumes for impacted PBS items
- The types of medicines dispensed within this overall volume
- Take-up of increased quantity prescribing by doctors
- Other demographic and regional variations.

Pharmacists and other pharmacy employees will save time through reduced patient-pharmacist interactions due to fewer dispensings for some medicines. This time may be spent on other patient related health care activities, including public funded health programs and services delivered in pharmacies.

Pharmacies may experience the loss of other sales revenue, as a result of reduced foot traffic through the pharmacy. The volume of medicines distributed by pharmaceutical wholesalers may also change.

Smaller pharmacies and those in isolated/remote areas may be impacted more than larger pharmacies and those in metropolitan areas, as in addition to reduced dispensing related remuneration, there may be less foot traffic and therefore less opportunity for over the counter sales due to the smaller populations of serviced regions. Under the 7CPA, regional, rural and remote pharmacies receive additional funding (Regional Pharmacy Maintenance Allowance (RPMA) program)⁴² to support the supply of medicines and healthcare in the community, to ensure access for all Australians to the medicines and pharmacy services required.

Alongside this proposal, the Government is considering proposals designed to mitigate the financial impact of increasing the MDQ by reinvesting savings back into the community pharmacy sector. The reinvestment package includes a proposal aimed specifically at rural and remote pharmacies and seeks to increase remote pharmacies, doubling the overall budget of Community payments under the RPMA program. It also seeks to provide an increase to the overall public investment in community pharmacy programs to ensure dose administration aids, medication management and review, opioid dependency

⁴² [Government boosts funding for community pharmacies to support more rural and regional communities | Health Portfolio Ministers and Aged Care](#)

treatment services and vaccination services can be offered by community pharmacies, and for existing programs, at levels above those for the 2022 calendar year, and above the level funded in the 7CPA.

The following table shows the Direct Regulatory Impact savings for pharmacists by increasing the MDQ for medicines – two months’ supply. It has been estimated that pharmacists, on average will save four and a half minutes per dispensing for over 66.8 million dispensings⁴³ by 2026-27. This will free pharmacists to participate in other patient health care related activities.

The following method and assumptions were used:

1. Pharmacists were estimated to save 4.5 minutes per dispensing avoided.⁴⁴
2. The estimated time saved (minutes) by pharmacists is 4.5 minutes x the number of dispensings avoided.

Table 4.2: Estimated dispensing time saved for Pharmacists by increasing MDQ to two months’ supply

Estimated dispensing time saved (minutes) by pharmacists				Total
2023-24	2024-25	2025-26	2026-27	
171,604,993	259,335,612	292,486,140	300,648,996	1,024,075,742

Source: 2023 Impact analysis costing-MDQ 2 month OIA22IA-03771

Prescribers

This proposal will give prescribers the option to consider prescribing higher quantities of some medicines to patients with chronic, stable conditions if appropriate.

When changes to the dispensing quantity were previously considered by the PBAC in 2018 it was publicly supported by medical stakeholders.^{45,46} In February 2023, the RACGP and the AMA supported the proposal and requested that it be reconsidered. However, some medical professionals may be concerned due to a higher quantity of the prescribed medicine potentially compromising patient safety and quality use of medicines. This risk is mitigated by the independent PBAC having recommended only medicines for chronic conditions that are considered clinically safe and suitable for dispensing in the community in higher quantities.

Prescribers will also retain the choice of clinically appropriate prescribing. Prescribers will be able to prescribe one month’s supply per dispensing and up to six months’ supply of a medicine per prescription, supporting closer clinical monitoring of patients where clinically required.

Many patients with chronic conditions may no longer be required to attend a doctor’s consultation at least twice a year to obtain their prescriptions for these medicines. These appointments will otherwise be taken up by other patients. It is anticipated prescribers will have the opportunity to use these

⁴³ Number of dispensing’s avoided based on forecasts 2023-03-24 TAAD Double MDQ costing, Department of Health and Aged Care

⁴⁴ Estimated by consultation with Department of Health and Aged Care with practising community pharmacists

⁴⁵ <https://www1.racgp.org.au/newsgp/racgp/government-backdown-on-dispensing-prioritises-prof>

⁴⁶ <https://www.smh.com.au/politics/federal/greg-hunt-shelves-plan-for-two-month-scripts-after-pharmacist-backlash-20190328-p518gw.html>

appointments to spend time with patients on more complex health issues and consultations, rather than writing repeat prescriptions for medicines to treat patients with chronic stable conditions. Over time, with improved patient medication adherence, there may be less need for prescribers to manage escalating health issues in patients not taking their medication as prescribed.

Pharmaceutical wholesalers

There are six Community Service Obligation (CSO) wholesalers who supply a majority share of PBS medicines to community pharmacy and are likely to be affected. However, there are a number of non-CSO wholesalers who do not have a specific arrangement with the Commonwealth but also supply some PBS medicines. As these additional suppliers are not regulated, it is not possible to estimate the total number of wholesalers that will be affected.

This proposal will result in the reduction of remuneration to wholesalers because of the way remuneration is calculated. Wholesaler mark-ups are derived according to legislative provisions.

The wholesaler mark-up for ready prepared pharmaceutical benefits is calculated as a percentage for medicines between the price of \$5.50 and \$720 (ex-manufacturer). For those products that fall outside this range it is applied as a flat fee for the maximum amount of medicine that can be dispensed. As a result, increasing the maximum dispensed amount in a PBS listing for any of these medicines, may reduce the amount of wholesaler mark-up paid by the Commonwealth overall.

Approximately 220 pharmaceutical items (the drug, form and manner of administration set out in the PBS listing⁴⁷) will have a reduced wholesale mark-up as a result of the listing of the increased quantity item for the two month supply option. The number of impacted pharmaceutical codes may change over time as PBS ex-manufacturer prices are subject to PBS pricing mechanisms such as price disclosure, anniversary price reductions and first new brand reductions.

The following example illustrates the effect of the two month supply option on wholesale mark up and pharmacy for a specific medicine, rosuvastatin 10mg tablet, 30 pack.

⁴⁷ <https://www.pbs.gov.au/info/industry/listing/procedure-guidance/shortened-forms-and-definitions>

Table 4.3 Primary impact – Two prescriptions for a one month supply become one prescription for a two month supply

Example – General beneficiary under two month MDQ option - medicine rosuvastatin 10 mg tablet, 30 pack.					
	Current arrangements		2 months' MDQ	Financial Impact	Notes
	1 month's supply	2 x 1 month's supply	1 x 2 month's supply		
<i>Ex-manufacturer price</i>	\$3.50	\$7.00	\$7.00	\$0.00	No impact on ex-manufacturer price
<i>Wholesale mark-up</i>	\$0.41	\$0.82	\$0.52	-\$0.30	The wholesale mark-up will reduce by \$0.30 across the two months of supply
<i>AHI Fee</i>	\$4.32	\$8.64	\$4.32	-\$4.32	One fewer AHI Tier 1 fee (\$4.32) will be paid across the two months of supply.
<i>Dispensing Fee</i>	\$7.82	\$15.64	\$7.82	-\$7.82	One fewer ready prepared dispensing fee (\$7.82) is paid across the two months of supply.
Dispensed Price for Maximum Quantity	\$16.05	\$32.10	\$19.66	-\$12.44	The overall dispensed price for 1 script of 2-month supply is \$12.44 less than for 2 scripts of 1-month supply.
Note: AHI = Administration, Handling and Infrastructure Fee					

Explanation: \$12.44 is the saving to the PBS as a whole for 2 x one month's supply of the medicine becoming 1 x two months' supply of the medicine.

How the \$12.44 saving is distributed between patients and the government depends on whether the patient holds a concession card or safety net card.

Table 4.4 Secondary impact - Flow-on to dispensed price of the existing PBS item code providing one month's supply

Secondary impact – Flow-on to dispensed price of the existing PBS item code providing one month's supply.			
	Current arrangements	Proposed arrangements	Financial Impact on existing one month's supply item
	1 month's supply	1 month's supply	
<i>Ex-manufacturer price</i>	\$3.50	\$3.50	\$0.00
<i>Wholesale mark-up</i>	\$0.41	\$0.26	-\$0.15
<i>AHI Fee</i>	\$4.32	\$4.32	\$0.00
<i>Dispensing Fee</i>	\$7.82	\$7.82	\$0.00
Dispensed Price for Maximum Quantity	\$16.05	\$15.90	-\$0.15
<p>Notes and Caveats: <i>Ex-manufacturer prices as at 1 April 2023.</i> <i>Fees and mark-ups are for the 2022-23 financial year (noting that fees will change on 1 July 2023 prior to the policy starting).</i> <i>The example is based on a single dispense of the maximum quantity.</i> <i>The example is for a specific medicine. The impact of this policy varies depending on the price of the medicine.</i> <i>This example accounts for components of the Commonwealth Price only, and does not account for discounting by pharmacy, additional allowable charges by pharmacy or brand premium payments.</i></p>			

Medicine sponsors

Initially, medicine sponsors may be required to increase Australian onshore stock levels due to a short-term increase in demand for certain PBS medicines. However, overall the same amount of medicine is expected to be supplied to the Australian market annually. A small financial gain in PBS revenue/rebate payments is expected for sponsors of medicines with a special pricing arrangement and/or a risk sharing arrangement, due to the expected impact of the proposal in reducing Commonwealth expenditure.

Medical and Dispensing Software Providers, Services Australia and Department of Health and Aged Care

Under usual PBS listing processes, there are limits to the number of changes that can be made to the PBS schedule each month. Implementation of this proposal may result in a very high volume of changes, meaning some other changes to the PBS Schedule may not be able to be progressed in that specific PBS listing month. This is both to ensure that prescribing and pharmacy software vendors and Services Australia are able to implement the high number of new items in their respective databases, but also to ensure that no errors are created in the PBS data where other changes may affect the same medicines that are subject to the MDQ changes.

Government

The cost of the PBS is expected to continue to grow over time, and this will put increasing pressure on the health budget.⁴⁸ This proposal will reduce PBS expenditure through:

- reducing dispensing and handling fees paid to pharmacists, as fewer prescriptions will need to be processed, and
- consumers will reach their applicable PBS Safety Net threshold later in the calendar year, or no longer reach their applicable PBS Safety Net threshold, as they will incur fewer co-payments early in the calendar year, and
- reducing the Safety Net card issue fees paid to pharmacists due to a smaller number of patients and families spending enough on PBS and RPBS medicines to reach their applicable PBS Safety Net threshold and be issued a PBS Safety Net card, and
- reducing the payments for the Electronic Prescription Fee for Prescription Exchange Services as the overall volume of PBS and RPBS prescriptions is reduced, and
- reducing wholesale mark-ups paid for those medicines which have prices where the wholesale mark-up calculation is impacted by the listing of the increased quantity items.

When two months’ quantity of medicine is dispensed at one time there is a risk of increased wastage, potentially increasing the cost of medicines to the PBS. This will be mitigated by the PBS restriction for these higher quantity items containing the following wording: “Patient’s condition must be stable and suitable for higher maximum dispensed quantity measure”.

Implementing the two month supply option may reduce the amount of medicine wastage, as double rather than triple quantities (Option 3) would be supplied at one time.

Regulatory burden estimate (RBE) table – Option 2

Average annual regulatory costs				
Change in costs (\$ million)	Individuals	Business	Community organisations	Total change in cost
Total, by sector	\$138,375,000 (save)	\$	\$	\$138,375,000 (save)

Option 3: Implement MDQ changes for medicines – 3 months’ supply

This option will require a significant number of new and amended items to be listed on the PBS schedule.

When fully implemented, the proposed changes could benefit a significant proportion of the base number of 9.6 million patients, when their prescriber’s assessment is that the patient’s chronic condition is stable and suitable for the higher maximum dispensed quantity item, by reducing the number of individual PBS co-payments they would have to make for medicines included in the MDQ proposal, and visits to the doctor and pharmacy may be reduced.

⁴⁸[https://www1.health.gov.au/internet/main/publishing.nsf/Content/4BC52286D3009386CA257BF000209AD5/\\$File/Impact%20of%20PBS%20Reform%20Report%203.pdf](https://www1.health.gov.au/internet/main/publishing.nsf/Content/4BC52286D3009386CA257BF000209AD5/$File/Impact%20of%20PBS%20Reform%20Report%203.pdf)

This option will have a bigger reduction to PBS expenditure compared to Option 2, provide a greater reduction in regulatory impact and greater savings in medicine costs for consumers than Option 2. This option has a higher financial impact to pharmacies than Option 2.

Consumers

Under this option, consumers will visit a pharmacy every third month instead of each month to have their prescription dispensed and may reduce their doctor visits.

In total, it is estimated that patients who are prescribed prescriptions at the triple maximum quantity will save around \$740 million in PBS patient contributions in 2026-27, and approximately \$2.5 billion between 2023-24 and 2026-27. Once fully implemented, this represents a further reduction in out of pocket costs for patients accessing PBS medicines compared to Option 2. In a similar way to Option 2, the estimated financial impact on consumers takes into account the financial benefit to the patient each time a dispensing of three prescriptions for one month's supply are replaced by a single prescription for three months' supply.

The subgroup of patients who receive **only** PBS medicines with increased MDQ items (approximately 1.89 million patients by 2026-27) have been estimated to save 15 minutes travel time and 20 minutes⁴⁹ attending a GP clinic annually and 120 minutes (8 visits x 15 minutes) attending the pharmacy annually.

All other impacts as for Consumers under Option 2.

The following table shows the Direct Regulatory Impact savings for consumers if the MDQ is increased to three months' supply for medicines included in the proposal.

It is estimated around 1.8 million patients will benefit in 2023-24, with total reduction in regulatory burden of approximately \$167 million. This increases to more than 1.89 million patients with more than \$175 million in reduced regulatory burden by 2026-27.

The following method and assumptions were used:

1. The base number of patients eligible was derived from PBS data. Around 9.6 million patients received two or more dispensing's of the PBS medicines in the list found suitable by the PBAC for increased MDQs in 2022. Of these, a subset of 1.77 million patients were only dispensed the increased MDQ medicines (and no other PBS medicines), therefore may benefit from fewer visits to the pharmacy and prescriber (GP).
2. At a population level, the assumed growth rate of PBS patient numbers per year is 1.6% based on ABS population projections. In 2023-24, it is assumed that the number of unique patients that will be prescribed more than one prescription for an MDQ item (but no other PBS subsidised medicines) will be 1.8 million.
3. Number of person minutes saved is GP visit x 1.8 million patients x 35 minutes (GP visit + travel time of 15 minutes) + 8 pharmacy visits x 1.8 million patients x 15 minutes.

⁴⁹ Level B Consultation as 1/2/2023

<http://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=23#:~:text=A%20Level%20B%20item%20will%20be%20used%20for,this%20should%20be%20reflected%20in%20the%20practitioner%27s%20record.>

4. Consumer/person time saved per pharmacy visit does not include travel time. GP offices and pharmacies may be co-located.
5. The default value for an individual's leisure time is estimated at \$36⁵⁰ per hour.
6. The estimated regulatory impact of the save is: (consumer/person minutes saved x \$36), divided by 60.
7. The estimated regulatory impact assumes a single implementation date in 2023-24.

Table 4.5: Direct Regulatory Impact savings for consumers by increasing MDQ to three months' supply

Number of times per year each patient affected				
2023-24	2024-25	2025-26	2026-27	TOTAL
GP visits saved per year				
1	1	1	1	
Pharmacy visits saved per year				
8	8	8	8	
Number of patients affected				
1,800,000	1,830,000	1,860,000	1,890,000	
Number of person minutes saved (annual)				
2023-24	2024-25	2025-26	2026-27	
279,000,000	283,650,000	288,300,000	292,950,000	
Estimated Regulatory Impact value of patient save (annual)				
2023-24	2024-25	2025-26	2026-27	Total
\$167,400,000	\$170,190,000	\$172,980,000	\$175,770,000	\$686,340,000

Source: 2023 Impact analysis costing- MDQMDQ 3 month OIA22IA-03771

*Average annual patient save: \$171,585,000

Pharmacies

The community pharmacy sector will be highly impacted by this option. This option has a higher financial impact to pharmacies than Option 2.

Under three month supply option, pharmacies will be paid one fee for dispensing three months' supply of a medicine on the one occasion, rather than one fee paid on three separate occasions for dispensing a month's supply of medicine over three separate months.

The impact on specific pharmacies will vary depending on the location of the pharmacy and its operating model. For the three month option, the estimated average impact per pharmacy in the fourth year following implementation may be up to \$210,000 reduction in remuneration, which is estimated to be a reduction of 24% of the baseline remuneration of community pharmacy fees (estimated to be \$867,000

⁵⁰ 2022 Regulatory Burden Measurement Framework | The Office of Impact Analysis (pmc.gov.au)

in the fourth year). PBS revenue is only one of the revenue sources for community pharmacies, and other sources of income are not captured in this analysis. The impact by individual pharmacy will vary considerably according to its operating model and factors such as:

- Dispensing volumes for impacted PBS items
- The types of medicines dispensed within this overall volume
- Take-up of increased quantity prescribing by doctors
- Other demographic and regional variations.

All other impacts as for Pharmacies under Option 2.

The following table shows the estimated dispensing time saved for pharmacists if the MDQ is increased to three months' supply for medicines included in the proposal.

It has been estimated that pharmacists, on average will save four and a half minutes per dispensing for over 89.1 million dispensings⁵¹ by 2026-27. This will free pharmacists to participate in other patient health care related activities

The following method and assumptions were used:

1. Pharmacists were estimated to save 4.5 minutes⁵² per dispensing avoided.
2. The estimated time saved (minutes) by pharmacists is 4.5 minutes x the number of dispensings avoided.

Table 4.6: Estimated dispensing time saved for pharmacists by increasing MDQ - three month option

Estimated dispensing time saved (minutes) by pharmacists				
2023-24	2024-25	2025-26	2026-27	TOTAL
228,726,540	345,764,277	390,009,505	400,899,510	1,365,399,833

Source: 2023 Impact analysis costing- MDQMDQ 3 month OIA22IA-03771

Prescribers

All impacts as for Prescribers under Option 2.

The impacts are the same as under Option 2 because under both options, each prescription with the increased MDQ will supply approximately 12 months' of medicine, an increase from 6 months under the status quo option. As such, under both Option 2 and Option 3, prescribers may see the same reduction in appointments from affected patients.

Pharmaceutical wholesalers

The impact on wholesaler remuneration may be greater under Option 3. The wholesaler mark-up for ready prepared pharmaceutical benefits is calculated as a percentage for medicines between the price

⁵¹ Number of dispensings avoided based on forecasts 2023-03-24 TAA Triple MDQ costing Department of Health and Aged Care

⁵² Estimated by consultation with Department of Health and Aged Care with practising community pharmacists

of \$5.50 and \$720 (ex-manufacturer). For those medicines that fall outside this range it is applied as a flat fee for the maximum amount of medicine that can be dispensed. As Option 3 provides a greater MDQ, the impact of the triple increased maximum quantity item in scaling down the calculated wholesale mark-up for impacted medicines may be more significant, further reducing the amount of wholesaler mark-up paid by the Commonwealth overall.

Medicine sponsors

Initially, medicine sponsors may be required to increase Australian onshore stock levels due to a short-term increase in demand for certain PBS medicines, and it would be assumed the effect of Option 3 would be greater than Option 2 due to the higher MDQ involved. However overall, the same amount of medicine is expected to be supplied to the Australian market annually. A small financial gain in PBS revenue/rebate payments is expected for sponsors of medicines with a special pricing arrangement and/or a risk sharing arrangement, due to the expected impact of the proposal in reducing Commonwealth expenditure.

Medical and dispensing software providers, Services Australia and Department of Health and Aged Care

All other impacts as under Option 2.

Government

Implementing the three month supply option is forecast to provide greater savings to Government than the savings forecast for Option 2. This option may increase the amount of medicine wastage, as triple rather than double quantities would be supplied at one time.

All other impacts as for Government under Option 2.

Regulatory burden estimate (RBE) table – Option 3

Average annual regulatory costs				
Change in costs (\$ million)	Individuals	Business	Community organisations	Total change in cost
Total, by sector	\$171,585,000 (save)	\$	\$	\$171,585,000 (save)

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

Some consultation on increasing the maximum dispensed quantities (MDQ) occurred after the initial PBAC recommendation in 2018 to increase MDQ to two months.

More recently a number of stakeholders have communicated publicly that they encourage the Government to reconsider this option, including the AMA and the RACGP.

As in 2018, the Pharmacy Guild of Australia (the Guild) remains unsupportive of the measure and argues that it would be preferable to increase the government subsidy on PBS medicines by further reducing the PBS general maximum co-payment (reduced on 1 January 2023 from \$42.50 to \$30) to \$19 in the May 2023 Budget. The Guild also argues that current supply shortages create challenges for some pharmacies in providing patients with one month's supply of medication.⁵³

On 10 April 2023⁵⁴, the Director of the Chemist Warehouse pharmacy chain supported the measure in principle but noted that “doubling the supply of common medicines may exacerbate medicine shortages”. He stated, “the measure could work well if there was a long lead time before the changes are made and the supply chain was right”.

The Government will hold consultations with key affected stakeholders in the pharmacy sector prior to the finalisation and/or announcement of these measures. Objectives of consultation for this proposal will be to educate, create awareness to expedite implementation and to inform evaluation.

PBAC

The PBAC provided advice on a similar proposal in 2018. The recommendations made by the PBAC were published on pbs.gov.au via its [August 2018 Outcome Statement](#) in April 2019. The PBAC provided advice and recommendations on the clinical safety and suitability of an extensive list of PBS items for inclusion in a proposal to increase the quantities per dispensing from one month's supply to two months' supply for patients with stable, chronic conditions.

In December 2022, the PBAC reconsidered its August 2018 advice around items on the PBS that could have increased maximum dispensed quantities of medicines for chronic conditions. The PBAC confirmed its 2018 recommendations, considered that a two or three month dispensed quantity would be clinically appropriate and expanded the list of medicines that could be included in the proposal. The recommendations for PBS items with higher dispensed quantities are in addition to, and not a replacement of, the current one month PBS listing for these medicines, allowing for appropriate decision making by prescribers.

The PBAC noted that the Government may choose to implement either the two or the three months' supply per dispensing and advised that the medicines recommended for inclusion in the proposal would

⁵³ <https://www.9news.com.au/national/doctors-call-to-double-length-of-scripts-pharmacy-guild-disagrees/b971e8a2-cd72-4608-bee5-79f9e5bf6bab>

⁵⁴ <https://www.9news.com.au/national/doctors-call-to-double-length-of-scripts-pharmacy-guild-disagrees/b971e8a2-cd72-4608-bee5-79f9e5bf6bab>

be appropriate for either option. Consistent with PBAC advice, existing listings would be retained alongside the new MDQ items, and prescribers will retain the ability to prescribe lower quantities where this is clinically recommended (for instance, where a patient needs more frequent monitoring on the medication).

The Pharmacy Guild of Australia

When consulted on the PBAC's similar August 2018 proposal, the Guild strongly opposed this measure, which reduced income for pharmacy owners.

This proposal is part of a package of proposals being considered by Government to mitigate the financial impact of increasing the MDQ by reinvesting savings back into the community pharmacy sector. The reinvestment package includes a proposal aimed specifically at rural and remote pharmacies, and also seeks to increase public funding for clinical services and programs, other than dispensing activities, delivered by community pharmacies. This will provide opportunities for pharmacies to provide a broader range of funded health services to the community and expand pharmacist scope of practice in community pharmacy.

The Guild's 'Distribution and Delivery of Pharmaceutical Benefits' policy states it 'believes that all Australians should have timely and affordable access to the full range of pharmaceutical benefits through their community pharmacy to achieve better health outcomes, consistent with the objectives of Australia's National Medicines Policy. A reliable, efficient and effective pharmaceutical distribution system is essential to achieving this'.⁵⁵

On 7 September 2022, the National President of the Pharmacy Guild expressed support for introduction of Commonwealth legislation to reduce the PBS General co-payment from 1 January 2023 to \$30, citing the Guild's advocacy on behalf of patients for a reduction to the cost of medicines.⁵⁶ On 10 April 2023, the Guild called for a further reduction to the PBS general maximum co-payment (reduced on 1 January 2023 from \$42.50 to \$30) to \$19 in the May 2023 Budget.⁵⁷

Royal Australian College of General Practitioners (RACGP)

In February 2023, the Royal Australian College of General Practitioners (RACGP) publicly stated⁵⁸ that the PBAC should revisit the 2018⁵⁹ recommendation to increase the maximum dispensed quantities on selected PBS items from one to two months' supply to reduce out-of-pocket costs, as well as the risk of patients missing medication dosages at the end of each month when their prescriptions run out.

⁵⁵ [PBS medicines supply \(guild.org.au\)](https://www.guild.org.au)

⁵⁶ Cheaper medicines a step closer - Pharmacy Guild of Australia

⁵⁷ <https://www.9news.com.au/national/doctors-call-to-double-length-of-scripts-pharmacy-guild-disagrees/b971e8a2-cd72-4608-bee5-79f9e5bf6bab>

⁵⁸ <https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2018-08/Outcome-Statement-August-2018-Increased-MDQ.pdf>

⁵⁹ <https://www1.racgp.org.au/newsgp/professional/gps-back-renewed-push-for-extended-dispensing-rule>

The RACGP⁶⁰ continues to be highly supportive of the proposal, stating the May 2023 Budget is an opportunity for government to reduce cost of living pressures for Australians by acting on reforms. Reasons put forward by the RACGP include to:

- extend the length of prescriptions to save patients money and time
- allow a larger supply of medicines in one go – a 2-month supply would halve dispensing fees, which cost taxpayers \$1.67 billion in 2021-22
- make prescribing faster and easier for GPs so they have more time for patient care by streamlining the PBS prescribing system, which is unnecessarily complex.

Australian Medical Association (AMA)

On 12 February 2023, the Australian Medical Association (AMA) called on the Government to implement the PBAC's recommendation to increase the maximum dispensed quantities on selected PBS medicine items from one month's supply to two months' supply, stating that patients could halve the costs of their medicines⁶¹.

Prescriber and dispensing software providers

Consultation will be undertaken through business as usual software vendor forums.

⁶⁰ [RACGP - Media releases](#)

⁶¹ <https://www.ama.com.au/media/ama-calls-two-months-medicines-be-dispensed-single-script-0#:~:text=%E2%80%9CBy%20doing%20this%2C%20for%20these%20particular%20medicines%2C%20patients,repeat%20medications%2C%20it%20would%20effectively%20halve%20the%20cost> .

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

Should the Government not implement either Option 2 or Option 3, there will be no additional benefits for consumers with chronic, stable medical conditions such as a reduced PBS co-payments, reduction in the number of visits to a pharmacy and reduced yearly out of pocket costs for some PBS medicines. Pharmacy owners will continue to dispense all PBS medicines for chronic conditions on a monthly basis, and receive similar revenue from dispensings and the associated fees and charges.

In December 2022, the independent PBAC noted that the Government may choose to increase the MDQ to either two month (Option 2) or three month (Option 3) supply. The PBAC advised that the list of medicines recommended for inclusion in the proposal would be safe and appropriate for either option.

Options 2 and 3 will provide more affordable access to PBS medicines for consumers for many chronic conditions and provide significant savings to Government by reducing dispensing related remuneration paid to pharmacy owners. The overall reduction in the number of PBS dispensings means some patients will reach their applicable PBS Safety Net threshold later in the calendar year and prescriptions lasting 12 months may contribute to fewer doctor visits for the sole purpose of renewing a prescription every six months.

Options 2 and 3 will result in fewer patients reaching the PBS Safety Net threshold, however these patients will save overall, as they will pay fewer PBS patient co-payments over the course of a year, due to the lower number of prescriptions needed to receive the same amount of medicine. Options 2 and 3 may also improve patient compliance to effective medicines, resulting in improved health outcomes and less burden on the Australian health care system.

Under Option 2, a significant proportion of the 9.6 million patients using medicines included in the proposal will collectively save around \$540 million in reduced PBS patient contributions in 2026-27, and approximately \$1.8 billion between 2023-24 and 2026-27.

For Option 2, a subset of approximately 1.89 million of these patients who use only PBS medicines with increased MDQ items for stable and chronic conditions (and no other PBS medicines) may save 35 minutes (consultation and travel time) attending a GP clinic annually and 90 minutes (6 visits x 15 minutes) attending the pharmacy annually. Patients who live in rural or regional areas or who find it difficult to visit a pharmacy each month may experience added convenience. In 2026-27, the total reduced regulatory burden for these 1.89 million patients is estimated to be more than \$141 million.

Under Option 3, a significant proportion of the 9.6 million patients using medicines included in the proposal will collectively save around \$740 million in PBS patient contributions in 2026-27, and approximately \$2.5 billion between 2023-24 and 2026-27.

For Option 3, a subset of approximately 1.89 million of these patients who use only PBS medicines with increased MDQ items for stable and chronic conditions (and no other PBS medicines) may save 35 minutes (consultation and travel time) attending a GP clinic annually and 120 minutes (8 visits x 15 minutes) attending the pharmacy annually. In 2026-27, the total reduced regulatory burden for these 1.89 million patients is estimated to be more than \$175 million.

Options 2 and 3 will result in owners of pharmacies and pharmaceutical wholesalers receiving reduced revenue associated with the dispensing of PBS medicines. In 2018, the Pharmacy Guild strongly opposed the two month option due to the reduction in income for pharmacy business owners, of which there are more than 5,900 across Australia.

The impact on specific pharmacies will vary depending on the location of the pharmacy and its operating model. Under Option 2, the estimated average impact per pharmacy in the fourth year following implementation may be up to a \$158,000 reduction in remuneration derived from Government paid PBS fees, which is estimated to be a reduction of approximately 18% of the baseline remuneration of community pharmacy Government paid PBS fees (estimated to be \$867,000 in the fourth year). For Option 3, the estimated average impact per pharmacy in the fourth year following implementation may be up to a \$210,000 reduction in Government remuneration, which is estimated to be a reduction of 24% of the baseline remuneration of community pharmacy fees (estimated to be \$867,000 in the fourth year). PBS revenue is only one of the revenue sources for community pharmacies, and other sources of income are not captured in this analysis.

Increasing the maximum dispensed amount for some of the included PBS medicines will also reduce the overall amount of wholesaler mark-up paid by the Government. There are six Community Service Obligation (CSO) wholesalers who supply a majority share of PBS medicines to community pharmacy and are likely to be affected. However, there are a number of non-CSO wholesalers who do not have a specific arrangement with the Commonwealth but also supply some PBS medicines. As these additional suppliers are not regulated, it is not possible to estimate the total number of wholesalers that will be affected.

Under Option 2, patients may save up to \$180 per year (General Beneficiaries) and up to \$43.80 per year (Concessional Beneficiaries) for each medicine prescribed for a chronic, stable medical condition. Option 2 out of pocket savings and regulatory savings for consumers are lower than those generated under Option 3 (for general patients up to \$240 per year and for concessional patients up to \$58.40 per year). However, the financial impact to the community pharmacy sector of Option 2 is less than for Option 3, noting that mitigation measures are proposed as part of these reforms to offset some of this impact.

Preferred option

The preferred option is that the two month MDQ option (Option 2) is implemented. This option will deliver significant savings to both patients and the Government compared to current policy settings (Option 1) and will have a more moderate impact on pharmacy and wholesalers than the three month option.

Implementation of the two-month option would give the Government the ability to retain the PBAC's recommendation for the three month option for later consideration, providing the opportunity to assess the financial impact of the two months dispensing quantity reforms on the network of pharmacies in Australia before proceeding to implement further changes, such as three months dispensing quantity reforms. In general, PBAC recommendations remain valid for two years.

In addition, Option 2 has been widely shared publicly as a concept, with the proposal well supported by medical and consumer stakeholders when recommended by the PBAC in 2018. It is likely minimal

consultation on Option 2 will be required, as only the number of medicines captured within the 2018 PBAC recommendation has been updated in the 2022 PBAC recommendation.

Implementation of Option 2 rather than Option 3 will result in the dispensing of less medicine quantity at one time (i.e. double rather than triple the current one month's supply). This may have two potential benefits:

1. allay the concerns expressed by some medical professionals in 2018 that the availability of large quantities of some medicines could compromise patient safety and quality use of medicines; and
2. potentially reduce the amount of medicine wastage and reduce any associated risk to Government of increased PBS costs.

Under Option 2 the risk of wastage is lower as only two months' supply of medicines is wasted instead of three months' supply if the patient develops a side effect or change in medical condition that means they do not continue taking the medicine.

Implementation of Option 2 rather than Option 3 may lessen the initial impact on medicine sponsors to meet an increase in Australian on shore stock levels of medicines. The amount of medicine supplied will not increase overall, and the increase will be offset once consumer demand for increased dispensed quantity prescriptions stabilises. The two month option may also place less pressure on logistics and supply chains in the initial implementation phase compared with the three month option.

This Impact Analysis assumes that implementation of Option 2 or Option 3 would occur on a single implementation date in 2023-24, following consideration of the proposal by the Government in the 2023-24 Budget. Delivering the recommended changes in a single instalment at the earliest opportunity would create the largest possible savings for both consumers and the Government. It would also minimise stakeholder and consumer confusion around medicine eligibility, given all changes would be available at the time of implementation.

Implementation

The Government will undertake consultation with key affected stakeholders in the pharmacy sector, including the Guild and other pharmacy stakeholders about the implementation of these proposals.

Consultation

The Government will conduct broader consultation with the community, including patient and prescriber groups following announcement. Objectives of consultation for this proposal will be to educate, create awareness to expedite implementation and to inform evaluation.

The Department of Health and Aged Care (Department) intends to undertake consultation and education of prescribers, all health professionals, consumers, medicine suppliers and software vendor representatives to expedite implementation and uptake as soon as any announcement is made.

Following a Government decision on the proposal, consultation will be undertaken by the Department with pharmacy representative groups, including the Guild, the National Pharmaceutical Services Association and the Pharmaceutical Society of Australia. Consultation with software stakeholders will also be undertaken by the Department, following a decision of Government. Consultation with other

stakeholders (including the general public) will be undertaken by the Department following any announcement.

The PBS Schedule is part of the wider PBS managed by the Department and administered by Services Australia. As part of implementation, the Department will consult and work collaboratively with Services Australia to ensure the significant volume of changes can be made and that systems can support the PBS Schedule changes. The Department and Services Australia have already collaborated to develop co-ordinated preliminary internal implementation plans to map the implementation process in preparation for a decision by Government. The Department is confident that the risk of unforeseen issues occurring during implementation is mitigated by this approach that encompasses a combination of consultation and well established business as usual processes.

Prescribing and dispensing software vendors will be consulted prior to implementation of the proposal through business as usual software vendor forums to ensure the new arrangements will be reflected in the software update for the chosen implementation month. Inclusion of the large volume of PBS Schedule changes (new PBS items and amended PBS items) into one monthly software update may mean that other PBS changes may not be progressed in the same month. Essential changes only for maintenance and proper functioning will be made to the PBS Schedule for that month. This is to ensure that prescribing and pharmacy software vendors, the Department and Services Australia are able to implement the large number of new items in their respective databases. It will also minimise errors created in the PBS data where other changes may affect the same medicines that are subject to the MDQ changes. Again, the Department is confident that the risk of unforeseen issues occurring and consequently unsuccessful implementation is mitigated by this approach that encompasses a combination of consultation and well established business as usual processes.

This proposal may result in increased pressure on the availability of doctor's appointments as consumers seek to access prescriptions for greater quantities of medicines while they still possess valid monthly prescriptions for their medicines. The Department will consult with prescriber representative organisations such as the RACGP and AMA to formulate strategies to manage demand on GP appointments. This may include targeted communication campaigns by the Department to manage consumer expectations.

Communications

The Department has commenced preparation of communication materials that will inform stakeholders of the feasibility of the chosen option and anticipate, address and respond to stakeholders' concerns about implementation. Communications with consumers and prescribers will provide clear and factual information about the PBS changes and expected benefits to patients. It will also ensure that the community is provided factual information about the interaction between co-payments and the PBS Safety Net and to alert prescribers to the changes so that they can adapt their clinical practice.

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

The Department of Health and Aged Care will develop a comprehensive evaluation framework that will monitor risks and provide mitigation strategies should unforeseen circumstances arise. The framework will utilise existing PBS evaluation processes and existing data sources (e.g. PBS claims data) where possible, and implement specific evaluation processes as required.

Comprehensive evaluation framework

The comprehensive evaluation framework will align with the objectives underpinning this proposal and may include:

1. *Improved and more affordable access to PBS medicines for people treated for many chronic conditions*

These objectives will be evaluated by reviewing the PBS statistics for the first quarter of implementation to establish baseline uptake of the proposal. Once 12 months of PBS data is available after the changes are implemented, the percentage of PBS prescriptions for medicines included in the proposal dispensed as MDQ items in the first year of implementation will be compared to the modelled estimates.

2. *Lower healthcare costs for consumers and Government without compromising patient safety*

This objective will be evaluated through monitoring the utilisation of the new MDQ items, quantity of medicine dispensed and quantifying the savings for patients once sufficient PBS data is available. This activity can be undertaken through routine research conducted by the PBS Post-Market Review program. These utilisation reviews would be considered by the Drug Utilisation Sub-Committee (DUSC) of the PBAC, and any concerns referred to the PBAC.

3. *Maintaining the sustainability of the PBS*

The cost of the PBS is expected to continue to grow over time, putting increased pressure on the health budget. To evaluate this objective, the total PBS Government expense for the supply of medicines for the 2023-24 financial year and following years will be monitored and compared with costs and annual percentage increases in previous years. To ensure the ongoing sustainability of the PBS, both the medicines subsidised and the programs through which medicines are supplied and accessed are reviewed regularly by Government.

4. *Quality Use of Medicines - Wastage*

As a result of implementing of Option 2 there is the potential for increased medicine wastage and cost to the PBS for medicines included in this proposal. However, the risk of wastage is mitigated by prescribers choosing the PBS item for increased dispensed quantities only for

patients with stable medical conditions. The PBS restriction for all items with increased quantities will include the following clinical criterion: *Patient's condition must be stable and suitable for the increased Maximum Dispensed Quantity measure.*

Any increase in the annual utilisation (quantity dispensed) of the medicines implemented with increased quantities may result inadvertently in more medicine wastage. Patients discontinue medicines for many reasons including a change in their condition or side effects meaning the additional quantities dispensed may be wasted. However, it will not be obvious if any increase in medicine utilisation is due to waste or increased adherence across the treated population taking these medicines.

Medicine wastage may be evaluated through the use of more complex drug utilisation research techniques using PBS unit record data. It is possible to determine the number of people initiating new treatment or discontinuing treatment early who have been prescribed two-month supply items. Assessment of adherence and persistence to treatment can also be measured based on PBS dispensing data. Such research can be requested and interpreted by the DUSC of the PBAC, should uptake and utilisation of the medicine items implemented in Option 2 be greater than expected.

The Return Unwanted Medicines (RUM) Project⁶² is funded by the Commonwealth Government through the Department of Health and Aged Care to address the Quality Use of Medicines (QUM) in Australia. The project facilitates the collection and disposal of unwanted medicines from the community. The project operates nationally with the cooperation of the pharmaceutical wholesalers and community pharmacies. The initiative provides consumers with a free and convenient way to dispose of expired and unwanted medicines. Medicines can be returned to any community pharmacy anytime, for safe collection and disposal. RUM collection data (in kilograms) has been available for comparison month by month by state since 2001.⁶³ To date, over 12 million kilograms of unwanted medicines have been collected. Any increase in the amount of medicines collected through this program may serve as a broad indicator of increased wastage, particularly if the trend correlates with the timing of implementation of the PBS items with increased quantities. However, this measure is limited, as the RUM program covers all medicines including over the counter and non – PBS medicines are collected.

5. *Quality Use of Medicines – Pharmacovigilance*

The Department's planned evaluation framework will utilise existing well developed processes within the Therapeutic Goods Administration (TGA) and the PBS program to assess outcomes of the implementation of Option 2 on patient safety and pharmacovigilance.

The PBAC has provided advice and recommendations on the clinical safety and suitability of a list of PBS items for inclusion in the proposal for patients with stable, chronic medical conditions.

The PBAC confirmed that only medicines or generics of medicines that have been PBS listed for

⁶² [Return of Expired and Unwanted Medicine | Home \(returnmed.com.au\)](http://returnmed.com.au)

⁶³ [Collection Results and Data | Return of Unwanted Medicine \(returnmed.com.au\)](http://returnmed.com.au)

five or more years are to be included in the policy, as severe but rare adverse effects frequently become evident during the first few years a drug is widely available.

Pharmacovigilance refers to monitoring the effects of medicines post TGA registration for use in Australia to identify and evaluate previously unreported adverse reactions. This is a 'business as usual' activity of the TGA, supporting the National Medicines Policy (NMP)⁶⁴ through ensuring medicines meet the required standards of quality, safety and efficacy.

The TGA has a pharmacovigilance program⁶⁵, which involves the assessment of adverse events that are reported to the TGA by consumers, health professionals, the pharmaceutical industry, international medicine regulators or by the medical and scientific experts on TGA advisory committees. There are strong linkages between the TGA and the PBAC. TGA representatives routinely attend PBAC meetings. Once the MDQ changes have been implemented, the Department will notify the TGA of the medicines included in the proposal. The TGA will continue to monitor all spontaneous reports of adverse medicine events submitted by healthcare professionals, patients or consumers and will inform the Department and the PBAC of any emerging trends in adverse reactions or medicine misuse associated with these medicines.

6. Quality Use of Medicines – Medicines shortages

Medicine shortages are routinely published on the TGA website.⁶⁶ Medicine sponsors inform the TGA if there is not enough medicine to supply normal demand in Australia within the next six months. The Department will monitor the Medicines Shortages website and liaise with the TGA to determine any impacts resulting from implementation of the proposal.

Monitoring stakeholder impacts

In addition to the development of a comprehensive evaluation framework to measure success and mitigate unforeseen issues, the Department is also committed to evaluating the impacts of implementation of the proposal all affected stakeholders through existing mechanisms.

Community pharmacy sector

The Department will continue to monitor the impact on the community pharmacy sector remuneration through existing 7CPA arrangements. The Department will monitor continued participation by community pharmacies in 7CPA programs, which are expected to continue at current levels with the reinvestment of Government savings from the proposal.

Evaluation of financial impacts will be dependent on affected stakeholders providing necessary financial information at a granular level to allow assessment of any variation in the impact on pharmacies in different settings (i.e. regional and remote). The Department will also monitor the number and

⁶⁴ [National Medicines Policy | Australian Government Department of Health and Aged Care](#)

⁶⁵ [TGA regulatory framework | Therapeutic Goods Administration \(TGA\)](#)

⁶⁶ [Medicine shortages: Information for consumers | Therapeutic Goods Administration \(TGA\)](#)

distribution of pharmacies across Australia to ensure businesses continue to be viable and provide convenient and affordable access to medicines for all Australians.

Wholesalers

The ongoing annual impact on wholesalers will be monitored by the Department through the existing 7CPA arrangements. Evaluation will be dependent on affected stakeholders providing necessary financial information.

Software vendors

The Department will continue to monitor impacts arising from implementation on software vendors through routine software vendor forums.